Tigecycline Matches Levofloxacin vs. Pneumonia

BY PATRICE WENDLING
Chicago Bureau

NICE, FRANCE — Tigecycline is as effective as levofloxacin in treating patients hospitalized with community-acquired pneumonia, results of a phase III clinical trial suggest.

Tigecycline appeared safe and was effective against the most common respiratory pathogens that have been observed in patients with community-acquired pneumonia.

There was no evidence of resistance to tigecycline in the study, which was conducted by 62 investigators in 22 countries, Dr. Nathalie Dartois said at the 16th European Congress of Clinical Microbiology and Infectious Diseases.

The findings are important in light of the increasing rate of hospitalizations associated with community-acquired pneumonia, and the continued increase in resistance to antibiotics such as penicillin, macrolides, and fluoroquinolones, said Dr. Dartois, of Wyeth Research, Paris; Wyeth Pharmaceuticals Inc. markets tigecycline under the brand name Tygacil and funded the trial.

Clinical cure was achieved in 89% of 144 patients in the tigecycline group, and in 85% of 136 in the levofloxacin group, among the 280 patients who were evaluable.

Levofloxacin, a fluoroquinolone, is sold under the brand name Levaquin.

Tigecycline is a first-in-class glycylcycline that was approved in the United States in June 2005 for treating complicated skin, soft tissue, and intraabdominal infections, and is pending approval in Europe. It has a broad spectrum of activity against gram-positive, gram-negative, anaerobic, atypical, and antibiotic-resistant bacteria, with the exception of *Pseudomonas*.

Tigecycline's extended postantibiotic effect is probably attributable to its long half-life, which is about 42 hours, Dr. Dartois said.

The study included 428 patients who were hospitalized with community-acquired pneumonia severe enough to require intravenous antibiotic treatment for at least 7 days.

The patients also had fever or hypothermia, new infiltrate seen on chest x-ray within 48 hours of admission, and at least two of the following: cough, purulent sputum, rales, dyspnea, increased white blood cell count, or hypoxemia.

Patients were randomized to tigecycline at an initial intravenous dose of 100 mg, followed by 50 mg every 12 hours, or to levofloxacin 500 mg every 12 or 24 hours.

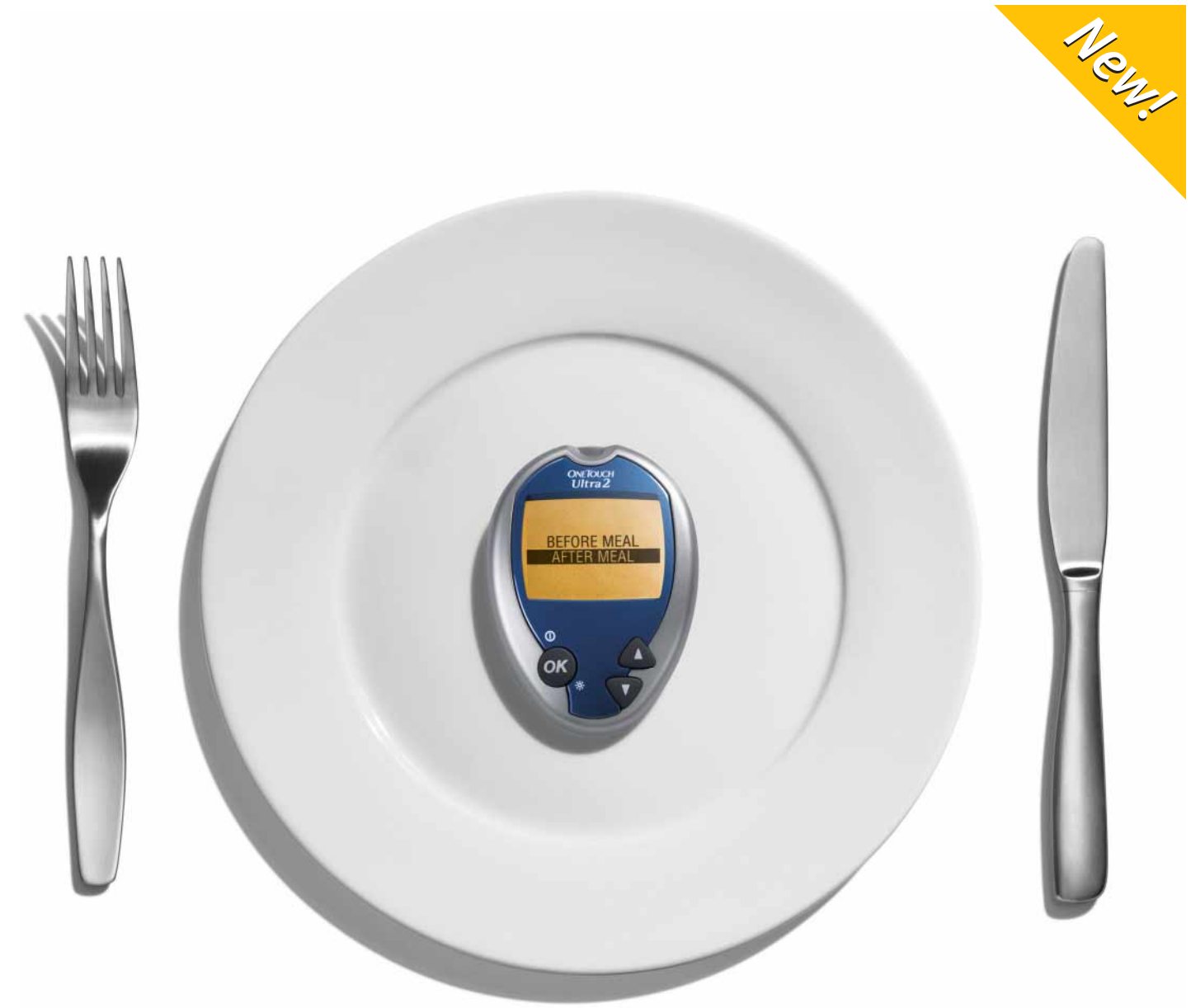
Coprimary end points of the study were clinical response in 280 clinically evaluable patients and 403 modified intent-to-treat patients assessed 10-21 days after the last dose. Demographics were similar in both treatment groups, and the majority of patients had a Fine pneumonia severity index (PSI) score that put them in risk classes II-IV. About 20% of patients had failed previous antibiotics. Their mean age was 49 years.

Of the 280 clinically evaluable patients, clinical cure was achieved in 128 (89%) of 144 patients in the tigecycline group, and 116 (85%) of 136 patients in the levofloxacin group.

Cure rates by patient PSI scores were 89.5% with tigecycline vs. 87% with levofloxacin in PSI risk class II patients, 85% vs. 83% in risk class III, 91% vs. 83% in risk class IV, and 100% for both agents in risk class V.

In the modified intent-to-treat population, tigecycline cured 170 (84%) of 203 patients and levofloxacin cured 163 (82%) of 200. Cure rates for the two most common isolates at baseline were 96% with tigecycline vs. 92% with levofloxacin for *Mycoplasma pneumoniae* and 93% vs. 94% for cultured *Streptococcus pneumoniae*.

Adverse events were reported by 62.5% of patients in the tigecycline group and 47% of patients in the levofloxacin group. Nausea, vomiting, and leukocytosis were significantly more common in tigecycline patients, whereas hypokalemia was significantly more common in levofloxacin patients. Treatment discontinuation rates due to adverse events were similar between the tigecycline and levofloxacin groups (6.5% vs. 8%), Dr. Dartois said. ■



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1. Hanefeld M, Schaper F. Prandial hyperglycemia: is it important to track and treat? Pharmacologic treatment of type 2 diabetes mellitus and obesity. *Current Diabetes Reports* 2005, 5:333–339.

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