Stent Thrombosis Rates Increase Over Time

BY MITCHEL L. ZOLER Philadelphia Bureau

VIENNA — The incidence of stent thrombosis following placement of drugeluting coronary stents suggested a possibly rising, curvilinear incidence during 3 years of follow-up of more than 5,000 patients treated at one center.

However, it's unclear whether late stent thrombosis rates increased at a linear rate or accelerated in a curvilinear way, Dr. Gregory J. Mishkel said while presenting a poster at the annual congress of the European Society of Cardiology.

Almost half of the stent thromboses occurred a year or more after stent placement while patients were still on dual antiplatelet therapy, which suggests that extended treatment with aspirin and clopidogrel provides only partial, long-term protection, said Dr. Mishkel, codirector of the coronary catheterization lab at the Prairie Heart Institute at St. John's Hospital, Springfield, Ill. The review included 5,342 patients at Prairie Heart who received their first drug-eluting coronary stent during May 2003–December 2006. Follow-up data were available for 5,173 (97%) of the patients; the average duration of follow-up was 1.8 years. Patients received an average of about 1.5 stents each; about 80% received sirolimuseluting stents (Cypher) and about 20% received a paclitaxel-eluting stent (Taxus).

During follow-up, 50 patients had a definite stent thrombosis, 13 had a probable

event, and 54 had a possible stent thrombosis. Among the 50 definite thromboses, 34 (68%) occurred a year or more after placement; 15 (44%) occurred while the patients were on dual antiplatelet therapy.

After the first 30 days, the rate of definite or probable stent thrombosis during the next 11 months was 0.2%. During the second 12 months of follow-up, the rate increased by 0.6%. During the last 12 months, the rate increased by another 0.7%, to a cumulative rate of 1.5%.

QUIT RATES SUPERIOR TO ZYBAN[®] AT 12 WEEKS IN 2 HEAD-TO-HEAD CLINICAL TRIALS (*P*=.0001)^{1,2*}

2 2 0 of subjects who received CHANTIX 1 mg bid quit smoking by the end of 12 weeks vs:

- Approximately 30% of subjects who received Zyban 150 mg bid
- Approximately 17.5% of subjects who received placebo

WELL-STUDIED TOLERABILITY AND SAFETY PROFILE

• The most common adverse reactions included nausea, sleep disturbance, constipation, flatulence, and vomiting. Nausea occurred in 30% of subjects while 3% discontinued due to nausea

CONVENIENT PAK DOSING

• PAKs are designed to simplify prescribing and to help improve patient adherence

GET QUIT SUPPORT PLAN

 A personalized behavioral support program designed to address critical behavioral components of smoking cessation, such as relapse

Patients should be encouraged to continue to attempt to quit if they have early lapses after quit day. Dosage adjustment with CHANTIX is recommended in patients with severe renal impairment or in patients undergoing hemodialysis.

Smoking cessation, with or without treatment with CHANTIX, may alter the pharmacokinetics or pharmacodynamics of some drugs, such as theophylline, warfarin, and insulin. Dosage adjustment for these drugs may be necessary.



TURN MORE SMOKERS INTO QUITTERS

*Results from 2 identically designed, 52-week (12 weeks pharmacotherapy, 40 weeks nonpharmacotherapy follow-up), randomized, double-blind, parallel-group, multicenter clinical trials (study 4: N=1022; study 5: N=1023) in which CHANTIX 1 mg bid was compared with Zyban 150 mg bid and placebo for efficacy and safety in smoking cessation. For trial inclusion, subjects must have smoked at least 10 cigarettes per day over the past year, with no period of abstinence greater than 3 months, and must have been bupropion naive. The primary efficacy end point in both trials was the carbon monoxide (CO)–confirmed 4-week continuous abstinence rate for weeks 9 through 12, defined as the percentage of subjects who reported no smoking (not even a puff) or use of any nicotine-containing products confirmed by an exhaled CO measurement of 10 ppm or less at each clinic visit. (Studies 4 and 5 from the CHANTIX package insert.)¹³⁵
Subjects were provided with an educational booklet on smoking cessation and received up to 10 minutes of smoking cessation counseling at each clinic visit in accordance with Agency for Healthcare Research and Quality guidelines.⁵