

**NEW CANADIAN STUDY FINDS DRUG COATED HEART STENTS TO BE SAFE:  
Effective in High Risk Angioplasty Patients**

**Toronto, Ont. -- October 3, 2007 --** Much controversy has developed over the past year about the safety and potential complications of drug-eluting heart stents, increasing the risk of possible fatal blood clots, even years after an angioplasty procedure. However, a new Canadian study led by investigators from Ontario's **Institute for Clinical Evaluative Sciences (ICES)** and McMaster University's Program for Assessment of Technologies in Health, tells a different story.

Drug-eluting stents were found to be most effective in reducing the need for repeat angioplasty procedures or bypass surgery in angioplasty patients at the 'highest risk' for a renarrowing of the artery around the stent, without significantly increasing the rate of death or risk of heart attack. Lead Author, **ICES** Sr. Scientist, Dr. Jack Tu says, "This is good news, reassuring patients and cardiologists about the safety of drug-eluting stents when used in appropriate individuals. Our results also suggest physicians should be selective in using drug-eluting stents, offering them to angioplasty patients who are at the highest risk for repeat cardiac procedures."

Reporting in the October 4<sup>th</sup> issue of the prestigious *New England Journal of Medicine*, the large Canadian study conducted at **ICES**, in collaboration with cardiologists and researchers from Sunnybrook Health Sciences Centre and the University of Toronto, looked at over 3,700 unique matched pairs of Ontario patients who received drug-eluting stents (DES) or more conventional bare metal stents (BMS) during angioplasty. Using data from the Ontario Cardiac Care Network's (CCN) population-based angioplasty registry, and accounting for differences in patient characteristics, investigators analyzed the outcomes of patients having angioplasty in Ontario between December 2003 and March 2005 for the 'real-world' effectiveness of DES. The results:

- DES reduced the need for a second procedure to unblock or bypass a clogged artery by 30% relative to BMS, from 10.7% to 7.4%.
- After 3 years of follow up, mortality was reduced for DES patients (5.5%) relative to BMS (7.8%).
- After 2 years of follow up, rate of heart attack for DES patients was marginally but not significantly higher at 5.7% vs. 5.2% in BMS patients.
- The reduction in the need for repeat procedures (i.e. target vessel revascularization [TVR rate]) was greatest in patients with two or three risk factors (e.g. diabetes, small vessels, or long lesions) for renarrowing of the artery, whereas lower and intermediate risk patients did not have significant reductions in TVR rates.

Co-Author, Dr. Eric Cohen, Medical Officer for CCN says, “Drug-eluting stents have been at the centre of a very active worldwide debate regarding issues of safety, degree of benefit and funding of a relatively expensive new technology. This study will be very helpful to clinicians, administrators and policy-makers in clarifying these issues as it confirms that using drug-eluting stents in patients at high risk for renarrowing is both effective and safe.”

Interventional Cardiologists use the tiny wire mesh tubes called stents to help prop open narrowed arteries after angioplasty, an artery clearing operation and a common medical procedure for treating angina and heart attacks. Prior to the development of stents, more than 20% of angioplasty patients required a second angioplasty or bypass surgery because of renarrowing of their coronary arteries. Both bare metal and drug-eluting stents enable blood to flow more easily through the artery by holding it open, with drug-eluting stents also leaking drugs to prevent tissue re-growth from re-clogging the arteries.

**ICES** Sr. Scientist, Dr. Jack Tu who holds a Canada Research Chair in Health Services Research at Sunnybrook Health Sciences Centre and the University of Toronto, says “Physicians implanting the devices need to ensure patients who get a drug-eluting stent also take anti-clotting medication such as aspirin and clopidogrel (antiplatelet therapy) for a minimum of one year after the angioplasty procedure. This therapy reduces the risk of fatal blood clots associated with drug-eluting stents. This prolonged period of clopidogrel usage could explain differences between results in Ontario, compared to those from other countries, such as Sweden. In our study, these medications were made available to all elderly patients in Ontario, at minimal cost, through the Ontario Drug Benefits Program for one year after the angioplasty procedure.”

Since their introduction in 2003, more than six million heart patients worldwide have received a drug-eluting stent (DES). The DES market is worth \$5 billion a year, costing about \$2300 for a DES versus \$700 for a bare metal stent (BMS). The rate of DES use in countries like the United States was as high as 90% but dropped to about 70% in the past year, after recent controversy over safety. Recent studies from Europe and Sweden suggest DES may increase mortality and heart attack after a coronary angioplasty. The rate of DES usage in Ontario was on average 38% of all stents during the study period. In 2003, the Ontario government approved the introduction of DES provincially, conditional upon an independent evaluation of their effectiveness and cost-effectiveness. Approximately 20,000 angioplasties are performed each year in the province of Ontario.

The study “Effectiveness and safety of drug-eluting stents in Ontario” is in the October 4<sup>th</sup> issue of the *New England Journal of Medicine*. The study was funded by operating grants from the Ontario Ministry of Health and Long-term Care and a Canadian Institutes of Health Research Team Grant in Cardiovascular Outcomes Research.

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resources. **ICES** knowledge is highly regarded in Canada and abroad, and is widely used by government, hospitals, planners, and practitioners to make decisions about care delivery and to develop policy.

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