

# St Vincent's Hospital

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## **LARGEST COMPARATIVE STUDY OF RADIOEMBOLISATION SHOWS SIR-SPHERES MICROSPHERES SIGNIFICANTLY IMPROVES SURVIVAL FOR CANCER PATIENTS WITH INOPERABLE LIVER TUMOURS**

### **New Australian data provides further evidence of survival benefit for radioembolisation**

Orlando, Florida (23 March 2012) – Findings from the largest comparative multi-centre study performed to date using radioembolisation report a significantly prolonged survival benefit following SIR-Spheres microspheres in patients with treatment-refractory liver tumours from colorectal and other cancers. The results of the study were presented today at the 65<sup>th</sup> Annual Cancer Symposium of the Society of Surgical Oncology, by Associate Professor Lourens Bester, Director of Radiology at St Vincent's Hospital, Sydney.<sup>1</sup>

Radioembolisation, which is also called Selective Internal Radiation Therapy or SIRT, is a novel approach to treating liver tumours using microspheres labelled with radioactive yttrium-90 (<sup>90</sup>Y). The microspheres are implanted by interventional radiologists to selectively target the tumours with radiation while sparing the remaining healthy liver tissue.

Prof. Bester and his colleagues evaluated 463 patients with chemotherapy refractory liver-dominant tumours and found that “radioembolisation is associated with a significantly improved and clinically meaningful survival benefit. Whilst confounding factors may play a role, offering this treatment may confer the best prognosis for these patients,” he said.

Among the 251 patients with colorectal liver metastases, median survival in the 220 patients treated with SIR-Spheres microspheres was 11.6 months, compared to only 6.6 months for the 31 patients who received standard or best supportive care ( $p=0.021$ ). In 212 patients with liver tumours from other cancers, including cholangiocarcinoma (41), neuroendocrine (40), hepatocellular carcinoma (27), pancreatic (13) breast (11), gastric (9) and other cancers (71), median survival was 9.5 months in the 180 patients treated with SIR-Spheres microspheres versus 2.6 months in 32 patients who received standard or best supportive care ( $p=0.013$ ).

“The significant improvement in overall survival in this study confirm the benefits demonstrated in two previous but smaller comparative studies that were performed in patients with treatment-refractory colorectal liver metastases, notably the multi-centre phase III randomised controlled trial conducted by Hendlisz and colleagues in Belgium, and the matched-pair analysis by Seidensticker and colleagues from Magdeburg, Germany, that reported median survivals of 10.0 and 8.3 months, respectively,” Prof. Bester added.<sup>2,3</sup>

Two large international randomised controlled trials are currently underway to evaluate the effectiveness of adding radioembolisation using SIR-Spheres microspheres to first-line chemotherapy in order to assess whether this treatment should be used as an early intervention in the treatment of patients with colorectal cancer liver metastases. In addition, three large randomised controlled trials are evaluating radioembolisation using SIR-Spheres microspheres in hepatocellular carcinoma.

## **About the study**

The aim of the study conducted at St Vincent's Hospital was to compare the outcomes of patients with liver tumours treated using radioembolisation with patients receiving standard or best supportive care alone in the setting of treatment-refractory disease.

All patients had chemotherapy refractory liver-dominant tumours with radiologically confirmed progression, and were no longer qualified for other treatment modalities such as resection, ablation or chemoembolisation.

The study excluded any patient with extensive extrahepatic metastases, symptoms that confined them to bed for more than 50% of the waking hours (ECOG performance status >2), excessive liver tumour burden (>75% of liver replaced by tumour) and/or compromised residual liver function.

Of the 463 patients who underwent initial evaluation for radioembolisation, 63 patients were considered unsuitable, due either to (a) hepatic arterial anatomy that could not be corrected and which could otherwise have led to complications, (b) extensive hepatopulmonary shunting between the liver and lungs, which raised the potential for excess radiation exposure to the lungs (>30 Gy), or (c) reasons relating to patient consent, such as a preference for another treatment option.

"The patients who were unsuitable for radioembolisation were referred back to their treating physician for conservative treatment or continued supportive care," explained Prof Bester. "This group was unlikely to represent patients with more advanced disease and was consequently used as a standard-care comparison cohort."

## **About Colorectal Cancer**

In 2008, 153,000 people in the United States of America and 333,000 in the European Union were diagnosed with colorectal cancer.<sup>4</sup> Around half of these patients will develop metastases that have spread from the original site of the disease, predominately to the liver. Up to 90% of these patients ultimately die from liver failure due to the spread of the disease.

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## References:

1. Saxena A, Chua TC, Meteling B *et al.* Radioembolization with yttrium-90 microspheres is associated with a significantly improved survival compared to conservative therapy after treatment of unresectable hepatic tumors: A large single center experience of 537 patients. *65<sup>th</sup> Annual Cancer Symposium of the Society of Surgical Oncology, Asia-Pacific Journal of Clinical Oncology* 2012; **7** (Supplement s4): Abstract 212.
2. Hendlisz A, Van den Eynde M, Peeters M *et al.* Phase III trial comparing protracted intravenous fluorouracil infusion alone or with yttrium-90 resin microspheres radioembolization for liver-limited metastatic colorectal cancer refractory to standard chemotherapy. *Journal of Clinical Oncology* 2010; **28**: 3687–3694.
3. Seidensticker R, Denecke T, Kraus P *et al.* Matched-pair comparison of radioembolization plus best supportive care versus best supportive care alone for chemotherapy refractory liver-dominant colorectal metastases. *Cardiovascular and Interventional Radiology* 2011; ePub doi: 10.1007/s00270-011-0234-7.
4. International Agency for Research on Cancer. GLOBOCAN 2008: Colorectal Cancer Incidence and Mortality Worldwide in 2008. <http://globocan.iarc.fr/factsheets/cancers/colorectal.asp> accessed 12/8/2011.

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