

26th April 2006

Ms Emily Marschke
Technology Appraisals Project Manager
National Institute for Health and Clinical Excellence (NICE)
MidCity Place
71 High Holborn
London
WC1V 6NA

Dear Ms Marschke

Health Technology Appraisal Ischaemic Heart Disease – Coronary Artery Stents

In our response to the original Assessment report submitted by the LRIg we expressed our concern about the methodology and data used to inform the Assessment report. After reviewing the Addendum (incorporating additional analyses as requested by the Appraisal committee) we are disappointed to see that none of our original concerns have been addressed. Guidant would like reiterate the following areas of concern:

- 1) Base revascularization rates estimated using single-centre data, ignoring more reliable international and UK data**
- 2) LRIg's methodology to estimate risk reduction from using DES in real-life**
- 3) Selective identification of risk factors for repeat revascularization**

1) In Table 5.1 (page 28) of the Addendum, LRIg list the total revascularization rates observed in various studies across the world. The corrected rates after applying LRIg-calculated adjustment factors range from 6.1% to 14.8%. Despite this LRIg have chosen to use CTC data which is a single centre data. We believe there is insufficient information on how this data was collected and hence quality of the data is questionable. Also because it is a single centre data, generalizability of the data to UK population and NHS practice is questionable. **In contrast, using more reliable and representative data (BASKET trial¹, SCRR 2003/4²) leads to a more realistic estimate of 12-14% base revascularization rate at 12 months.**

2) The original Assessment report concludes that DES effectiveness in reducing TVR is much lower (35-46%) than observed in clinical trials (57.5%). For this they give several reasons including *"selecting reporting of results (bias against negative publishing)"*, *"practitioners participating in RCTs are generally enthusiastic volunteers"*. The Group has used CTC data to inform their conclusion which as highlighted above introduces bias into the entire analysis. Further, the use of Total Revascularizations as an end-point (instead of looking at TVR/TLR) introduces additional statistical uncertainty into the analysis.

3) Long lesions, small vessels and diabetes are the most commonly identified risk factors for revascularization. LRIg have selectively used data to rule out diabetes as an independent risk factor. Notably, Health Technology Assessments in other European countries have recognized diabetes as an independent risk factor along with long lesions and small vessels (AFFSAPS France³)

Based on the above comments we feel that the original report has been heavily biased by the Bagust et.al⁴ publication – which was an outlier in terms of its reported clinical and cost effectiveness results. This has not been addressed in the Addendum report despite the request from the Appraisal Committee. In conclusion we are concerned that using this analysis to inform decision making by the Appraisal Committee may adversely impact the lives of thousands of patients in the UK.

Yours sincerely

Guidant UK Country Manager
Vascular Intervention

References

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2. Pell J, Slack R. The Scottish Coronary Revascularisation Register: Annual Report 2003-2004: NHS Scotland; 2005
3. Assurance Maladie website accessed on 21st April 2006.
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4. Bagust A, Grayson AD, Palmer ND, Perry RA, Walley T (2005). Cost-effectiveness of drug-eluting coronary artery stenting in a UK setting: cost-utility study. *Heart* Apr 14; [Epub ahead of print]
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