DR. DIAMOND'S NOVOSTE REVIEW

ACMUI Colleagues:

As a preface to my remarks I note that 1) I have reviewed the Novoste event data, and 2) that I have had extensive personal experience with least 2 iterations of the Novoste device, as well as with the two other commercially available intravascular brachytherapy systems.

I myself have experienced no events with the Novoste system.

I believe the root cause for these reported events derives from a design which relies on hydraulic pressure to propel a series of small, unconnected solid sources anterograde and retrograde through the catheter system. As such, perterbations which produce transient loss of positive hydraulic pressure (including loss of hydraulic fluid, catheter kinking, or catheter obstruction) may cause the seeds to not reach their desired distal dwell position, migrate from their desired dwell positions during treatment, or impair them from returning to the source delivery unit at the conclusion of treatment.

A secondary root cause for these events would include the failure of operators to quickly identify inappropriate seed positioning. This failure could be the result of operator inexperience (both AU and interventional cardiologist), suboptimal fluoroscopic/cine imaging capabilities, and a distal/proximal "marker seed" design which can at times be difficult to distinguish from the interposed therapeutic sources.

My thoughts, therefore, generally parallel those of Dr. Nag's from his memo of October 8, 2003.

The ACMUI will need to deliberate whether the current rate of new Novoste events (keeping in mind that many--but not all--of these events pose no threat to patient safety) mandates a design change, or whether this goal can be met through better education regarding the secondary root causes.

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