

DR. NAG'S REVIEW OF NOVOSTE EVENTS

To NRC and ACMUI:

Let me start the ball rolling so this can be a starting point for discussion. The following are my personal views. I have used several intravascular brachytherapy systems, but not the Novoste since I did not feel I could rely on its design.

The Novoste system is very convenient as it is small, hand-held and uses a beta source, obviating the need for shielding. The system relies on hydraulic pressure from saline to move a number of Strontium sources. Unlike the other intravascular systems where the source is (or sources are) physically attached to a wire, in the Novoste system there is no physical attachment. Herein lies the weakness of the system. If there is even a mild resistance, narrowing or obstruction of the catheter, the saline is able to flow but not the sources. In a tortuous vessel like those in the coronary system, the catheter will not be straight and the curvatures in the catheter will introduce resistance to flow. This can (and does) result in the following:

1. The sources may not reach the end of the catheter (site of intended radiation) hence irradiating a segment of the vessel proximal to the intended site.
2. After reaching the site of irradiation, the sources may not be able to return back to the Novoste system. This can result in increased radiation of the treatment site or irradiation of vessel site proximal to the target.
3. The sources may break up, rather than travelling together end-to-end hence irradiation sites proximal to the target and not irradiating the target.

The commonality and the root cause of most of the events is the design of the Novoste system whereby there is no direct attachment between the sources themselves and between the sources and the force moving the sources.

The ACMUI will have to discuss whether incidence of medical events (misadministrations) with the Novoste is acceptable or whether Novoste will have to change its design so that the sources are physically held together and physically attached to a wire (or similar device) that will be able to exert a force to move the sources reliably in either direction within the catheter.

Thanks for allowing me to express my thoughts.