VASCULAR SOCIETY OF GREAT BRITAIN AND IRELAND

BSET British Society of Endovascular Therapy

British Society of Interventional Radiology
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Surveillance Advice for Clinicians and Patients with Medtronic Valiant Navion Thoracic Endografts.

Medtronic has recalled the global stock of all Valiant Navion stent grafts following identification of some potential defects leading to stent ring dilatation in a small number of patients. Thus far, this seems to involve a very small proportion of devices and is limited to those implanted to treat aneurysms. It is unclear at the moment how widespread this is and what the durability implications are. Advice has already been given to stop using these grafts and Medtronic has restocked with Valiant Captivia devices.

It is estimated that about 450 such devices have been supplied to the UK market since introduction in 2018. This is thought to involve between 250-300 individual patients, the majority of whom would be having annual CTA surveillance. Most will have been used to treat atherosclerotic aneurysms or type B aortic dissections, but some may have been used for blunt aortic injury following trauma in younger patients. As the changes identified are subtle, they may not be identified during conventional surveillance imaging.

From a duty of candour perspective, we would advise the following:

1. All Trusts should check whether they have used Medtronic Valiant Navion stent grafts and compile a list of patients treated.
2. All patients known to be alive should be contacted to inform them of the situation. A sample letter is attached which can be modified for local use.
3. Previous imaging should be re-reported to specifically compare stent ring diameters at the time of implant, with the most recent imaging diameter (throughout the whole length of the graft). Medtronic believes an increase in diameter of 3mm or greater is significant. Stent fractures and type III endoleaks should also be actively excluded. This process will require reconstruction of images and multiple measurements on a workstation. Any patient who has not had imaging within the last 3 months or if previous imaging was of insufficient quality, should be advised to have another CTA.
4. Any abnormal findings should be forwarded to your local Medtronic representative and a Yellow card completed for the MHRA.
5. Medtronic has advised continuing with annual CTA surveillance as a minimum, but in light of possible anxiety, we feel patients should be offered enhanced surveillance at 6 monthly intervals if they are concerned or if any dilatation is identified. This can be re-assessed when further information is available.
6. Patients with any major adverse findings should be considered for re-lining with an alternative stent graft if appropriate clinically.

7. There should be a low threshold for re-lining in any such patient presenting with new unexplained sac dilation or symptoms.

As further evidence becomes available, the guidance will be updated. Medtronic is currently developing a platform to aid measurements for surveillance and we anticipate this will be available soon.

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