Early Fracture of Implanted Central Venous Catheter Inserted Percutaneously through Subclavian Vein

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Your attention is drawn to two adverse events in relation to Totally Implantable Venous Access System in the past 12 months.

Device:
Totally Implantable Venous Access System (TIVAS), consisting of an implantable reservoir compartment (the port) that has a self-sealing septum for repeated needle insertion and an implantable Central Venous Catheter (CVC) for fluid delivery or blood sampling.

Intended Uses of the Device:
TIVAS is intended to permit repeated intermittent access to the vascular system for the parental delivery of medications, fluids and nutritional solutions.

Problem:
Two incidents of early fracture of CVC of TIVAS have been reported to this Department. The two fractures were discovered at about 12 months and 18 months post-implantation. In both cases the CVCs were placed percutaneously via the subclavian vein. In one case the catheter was completely transected and the distal portion of the broken catheter migrated to the right atrium. Open heart surgery was required to retrieve the broken part.

The root cause of the two incidents could not be conclusively determined based on available evidence. A possible explanation was that the fractures were caused by repeated external compression (or "scissoring action") of the CVC in the costoclavicular space by the clavicle and the first rib, a condition known as Pinch-Off Syndrome (POS).

POS is usually seen with the percutaneous subclavian approach. When the catheter is inserted medial to the midclavicular line, it will be positioned outside the subclavian vein in the costoclavicular space and enter the subclavian vein through its medial wall. This position predisposes the catheter to compression and scissoring action between the first rib and clavicle in the costoclavicular space. Repeated compression can weaken the catheter and cause catheter fracture or even complete transection. A more lateral approach will position the catheter within the vein when it is passing through the costoclavicular space, where the angle between the first rib and the clavicle widens, and thus by geometric considerations it is not subject to compression.

POS is a known complication of TIVAS. The incidence is about 1% in patients fitted with TIVAS. It is most commonly detected shortly after catheter placement, but delayed presentation has also been reported. It can result in intermittent mechanical occlusion of the catheter, fracture of the catheter, or even complete catheter transection and embolization into the central venous system. It is identified primarily through clinical findings (such as intermittent occlusion or resistance to flow with different shoulder positioning) and substantiated through radiographic

findings (such as catheter luminal narrowing between the first rib and clavicle when the patient's arms were at sides when standing upright).

Recommendations:
If percutaneous subclavian approach is to be used, the procedure should be performed by experienced doctors. According to the "Instruction for Use" of the TIVAS, medial insertion of CVC should be avoided. The access site should be at or lateral to the midclavicular line and prior to the vein entering the thorax at the costoclavicular space. Alternative approaches, such as surgical cutdown approach or percutaneous approach at other sites, should also be considered in case of difficulty.

After implantation, a chest x-ray should be made, with patient upright and arms at sides. This can be used to evaluate, in addition to CVC tip location and other potential insertion complications, the position of CVC to ensure that it is not being pinched.

Please bring this notice to the attention of your staff/members concerned. Should you have any enquiry, please feel free to contact the Medical Device Control Office (Tel: 3107 8483; Fax 3157 1286; Email: mdco@dh.gov.hk).