REDUCe2 LTAD Leakage Troubleshooting Guide

We have noticed that leakage is currently one of the most common ARs/SARs in the intervention group. As we mentioned in previous TMG meetings there is also a rate of leakage in patients with LVPs, but we suspect this is being underreported – so please make sure you ask about this specifically at the fortnightly research visits in the SOC arm.

Occasional leakage from the LTAD may occur and is somewhat expected, but this requires prompt attention to prevent complications**. Please ensure the PI is made aware as soon as possible and the following guide is used for troubleshooting potential causes:**

Early leakage
This is not uncommon and starts to decrease after the first couple of weeks. Ensure that much ascites as possible is safely drained in hospital with HAS cover after the LTAD is inserted

1.1 Inadequate securement – This can lead to unintentional dislodgement and leakage. Ensure that the suture at the insertion site is close to the skin and not too long. Ensure the cuff is not exposed and is in place under the skin. The cuff sitting in the correct place will promote fibrous tissue ingrowth which helps with securing the drain in place and preventing leakage and infection.

1.2 Inadequate closure of the skin at the insertion site – Check for proper closure at the insertion site, and consider additional sutures if needed. Consult the PI if unsure.

1.3 Poor dressing integrity or positioning of the patient – In the initial days post LTAD insertion, manage common leakage with absorbent dressings provided by the medical device company and ensure they are placed securely. Advise patients to lie on the opposite side to minimize fluid contact with the insertion site with the help of gravity.

1.4 Excess build-up of ascites – Patients might be accumulating fluid faster than the volume drained. Consider increasing the frequency or volumes of fluid drained. Please inform the PI and CI if they are already at the maximum 5L/week in the protocol. It is safe to continue draining > 5L/week if tolerated by the patient – but only a small proportion will need this.

Late leakage
This is less common. In addition to the above potential causes please consider the following:

2.1 Drain blockage – Ensure smooth fluid flow from the drain. If flow is poor, consider flushing the drain to prevent blockage. Report to the PI as this might need to be done in a day case unit.

2.2 Valve failure – This can cause leakage of fluid when the cap is removed; the valve can be replaced at the bedside. The medical device company rep and the trial management team can provide some assistance.

2.3 Tissue irritation – Timely removal of sutures, as per protocol, can mitigate cellulitis or tissue irritation. If maceration of the skin occurs, briefly expose the site daily in an optimal position (refer to point 1.3) to help drying of the skin.

2.4 Tissue infection – Contact the PI if infection concerns persist despite prophylactic antibiotics. Consider antibiotic treatment and an ascitic tap to rule out SBP and peritoneal cavity infection.