In the appendix from the study by Bolinder and colleagues, the authors reported 13 cutaneous adverse events related to the use of FreeStyle Libre. In total 10 patients were experiencing these adverse events. The reported events were categorised as:

- Mild (3 cases)
- Moderate (4 cases)

All 7 cases required drug therapies, and 3 of them were discontinued from the study.

- Severe (6 cases).

2 patients were discontinued from the study and 2 patients with severe skin adverse events were treated by drug therapy.

The fact that patients with skin adverse events might decide to continue or discontinue their participation in the trial, seemed reasonable.

But the management of these adverse events remains unclear and not proportional to the severity of the adverse events. It would be helpful if the authors can determine clearly what type of device-related skin adverse events require treatment or device discontinuation, or both.

Abbott comment

Request to the authors of the IMPACT trial to advise what type of device-related skin adverse events requires treatment or device discontinuation, or both.