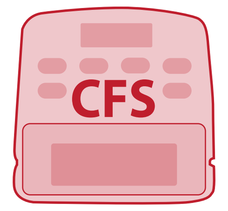
Improving Patients Subcutaneous Immunoglobulin (SCIg) Treatments Through Right Selection of Infusion Device Technology

Background

Previous studies have shown the importance of ancillary supplies on outcomes and corrective action dealing with local-site adverse events (AE's) during SCIg administrations. The infusion device employed is a significant part contributing to the overall performance of all elements connected together in the delivery system to perform the infusion. There are three types of infusion devices available for SCIg infusions. Each one creates different characteristics to support a successful SCIg infusion outcome: electric type constant flow system (CFS), mechanical devices using variable coiled spring pressure (VSP) and mechanical constant pressure system (CPS).



Constant Flow Systems (electronic); programmed to a specific flow rate, respond to tissue saturation by increasing pressure.

Variable Coiled Spring Pressure ( ) systems use pressure of a coiled spring; as spring expands, the pressure decreases (pressure fall-off).

Constant Pressure Systems ( ) respond to tissue saturation by slowing down to maintain safe pressure throughout infusion.

Purpose

Identify the infusion device most appropriate for SCIg administration with considerations to the ancillary supplies, such as the subcutaneous needle set (SNS) and flow rate control device. Each system has advantages and disadvantages affecting the overall therapeutic outcome.

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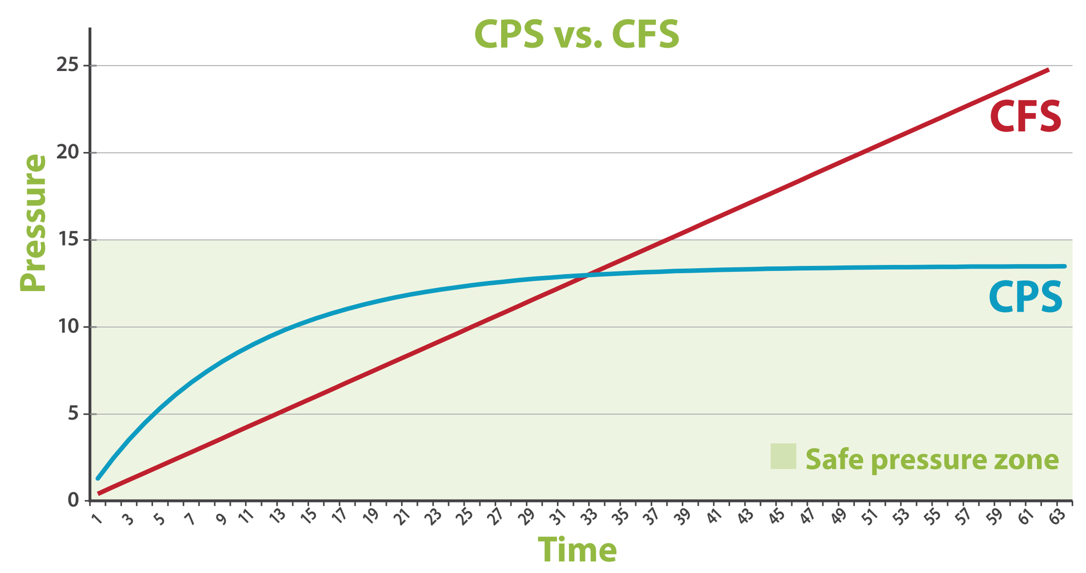
Methods

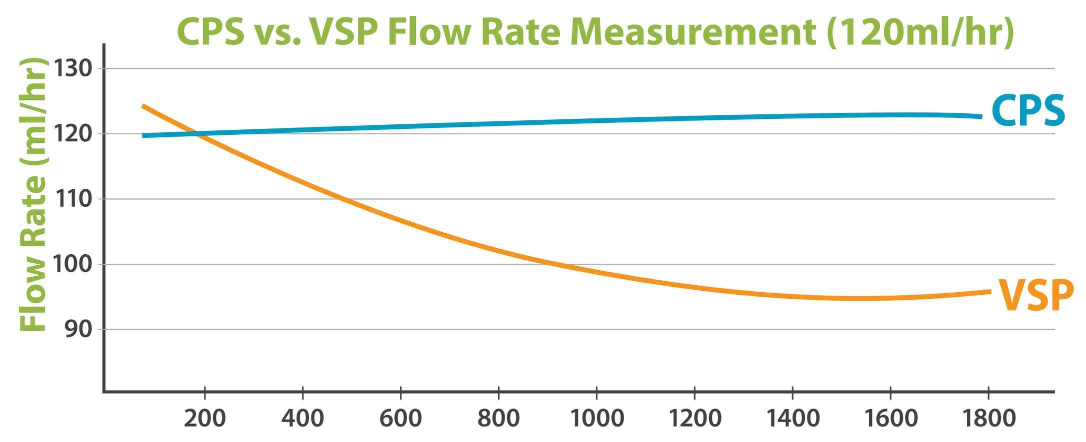
Laboratory tests and clinical experiences have confirmed theoretical models of the three types of infusion devices and systems; CFS, VSP and CPS. The test in the laboratory included simulation of patient sites (depots) when different infusion devices where applied. Pressure at the outlet of the device or pump, and the distal pressure at the simulated patient depot were measured, recorded and compared.

Recorded Data of Infusion Devices:



CPS - Maintains a constant pressure from start to end and through-out duration of the infusion. Flow rate is controlled by the resistance in the flow rate tubing, high flow 26G subcutaneous needle set, viscosity of the drug, and the ability of the patient's infusion site to accept drug.

CFS - Maintains a certain flow rate. Pressure varies based on the resistance of the tubing and needle sets, drug viscosity, site acceptance, and occlusion (overpressure) alarm setting.



CPS - The system generates a stable and constant flow rate throughout the infusion. Flow rate is controlled by the resistance of flow rate tubing plus low resistance high-flow needle sets, along with the acceptance of medication at the patient's infusion site.

VSP - The patterns for coiled spring systems demonstrate the flow rate being significantly higher at the beginning of the infusion versus the end. As medication is dispensed, pressure of the condensed spring decreases (pressure fall-off) against the decreasing volume of drug remaining in the reservoir.

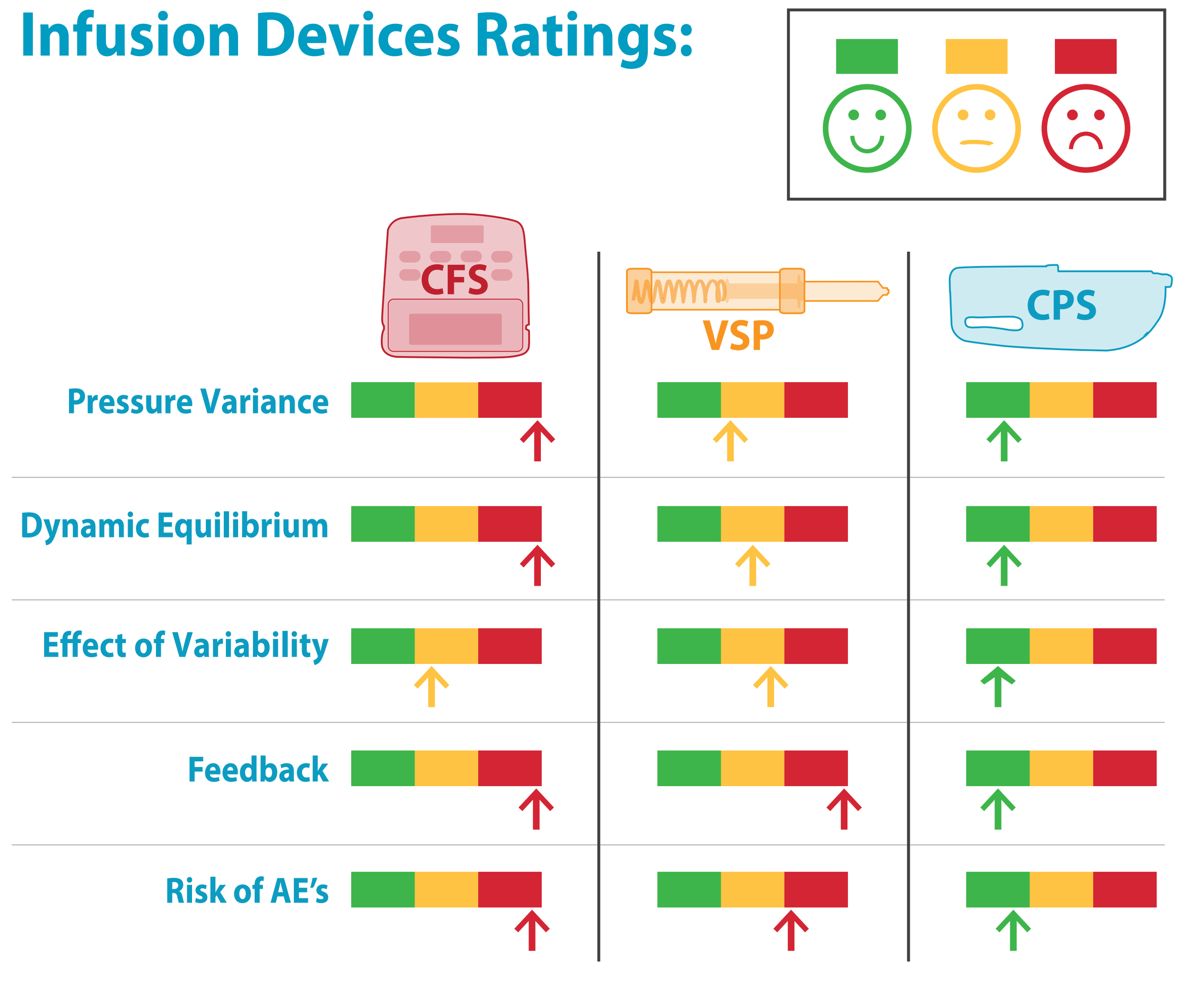
Results

The results for the CFS show that as the depots saturate, the pressure at the simulated patient infusion-site and at the pump outlet increase. This process continues until the pressure (occlusion) alarm is activated.

The VSP shows decreasing pressure as fluid is delivered. This is a normal consequence of any coil spring as the force will drop with increasing distance. As a result, the measured pressure at the pump decreases during the delivery, resulting in decreasing flow rate.

The CPS shows a constant pressure at the pump independent of the volume delivered or the patient infusion-site pressure. The CPS reduced the flow rate in direct proportion to the simulated tissues saturation. For mechanical pumps and devices the flow rate is related to the differences in pressure between the pump and the patient depot.

Infusion Devices Ratings:



Conclusion

The CPS demonstrated significantly lower pressures than CFS and more consistent flow rate performance and pressure control than VSP. For SCIg administrations, the CPS response to infusion-site saturation provides an improved level of safety and comfort, reduction of AE's and increasing patient compliance. AE's can be minimized and reduced through lower infusion pressures, defined and controlled flow rates limiting delivery when tissue perfusion is compromised as the patient's infusion-sites are saturating.

CPS is the system of choice:

- Significantly lower pressure than CFS
- More consistent flow rate performance and pressure control than VPS
- Responds to infusion-site saturation and provides feedback to improve level of safety and comfort
- Adverse effects can be reduced with:
  - Lower infusion pressures
  - Defined/controlled flow rates

References:

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