Unintended primary infusion from incomplete closure of administration set back-check valves at various head-height differentials and secondary flow rates

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Background
- Large volume peristaltic infusion pumps deliver secondary medications, “piggy-back”, through the primary administration set
- This secondary infusion system requires the use of a back-check valve in the primary set to prevent primary flow during secondary infusion
- The back-check valve closes and prevents primary flow from hydrostatic pressure from two IV bags hung at differing heights creating a fluid head-height differential
- Clinical literature includes reports of intended primary infusion (“sympathetic flow”) during secondary delivery
- Back-check valve failure may result from inadequate head-height differential, high secondary flow rates, incomplete opening of the secondary connector to the primary line, or in the back-check valve, back-check valve component defects

Purpose
- To evaluate whether back-check valve failure and unintended primary flow occurs at clinically relevant combinations of head-height differentials and secondary flow rates

Methods
- Two identical, commercially available infusion pumps utilizing administration sets with back-check valves were selected
- The pumps were programmed to deliver secondary infusions at head-height differentials of 0, 4, 8, 16, or 20 inches
- At each head height differential, the secondary infusion was infused at 100, 200, 300, 400, or 500 mL/hr
- For all testing, the height differential of the secondary bag in relation to the pump was per the user manual (24 inches)
- The primary outcome measure was the total volume of sympathetic flow delivered in each infusion scenario
- The secondary outcomes were the flow rates from primary and secondary containers over time
- The amount of fluid delivered from the primary, from the secondary, and to the outlet beaker were each recorded continuously per gravimetric methods in IEC-60601-2-24

Results

Conclusions
- During a programmed secondary infusion via a peristaltic pump, sympathetic flow from the primary container was observed with decreasing head-height differentials and increasing programmed secondary flow rates
- Unintended sympathetic flow occurred with both pumps consistently when flow rates increased and head-heights decreased
- High flow rates lead to sympathetic flow even when head-height differential aligned to manufacturer recommendations
- In clinical circumstances when bag position options may be constrained, lower head-height differentials may lead to incomplete closure of the backcheck valve and significant sympathetic flow
- The potential patient impacts from sympathetic flow are delayed secondary medication administration, delivery of the primary fluid at the programmed secondary rate, and clinician confusion on remaining secondary fluid after a “completed” programmed piggyback infusion
- Further studies are required to confirm and evaluate the clinical significance of these results

Directions for further study
- Obtain data from an increased number of pumps and administration sets with the studied infusion platform
- Expansion of testing to other peristaltic pumps and administration sets
- Evaluation of results with consideration of pumping mechanism, back-check valve manufacturer, secondary connector
- Expansion of research to clinical observations of secondary head-heights and programmed secondary rates

References