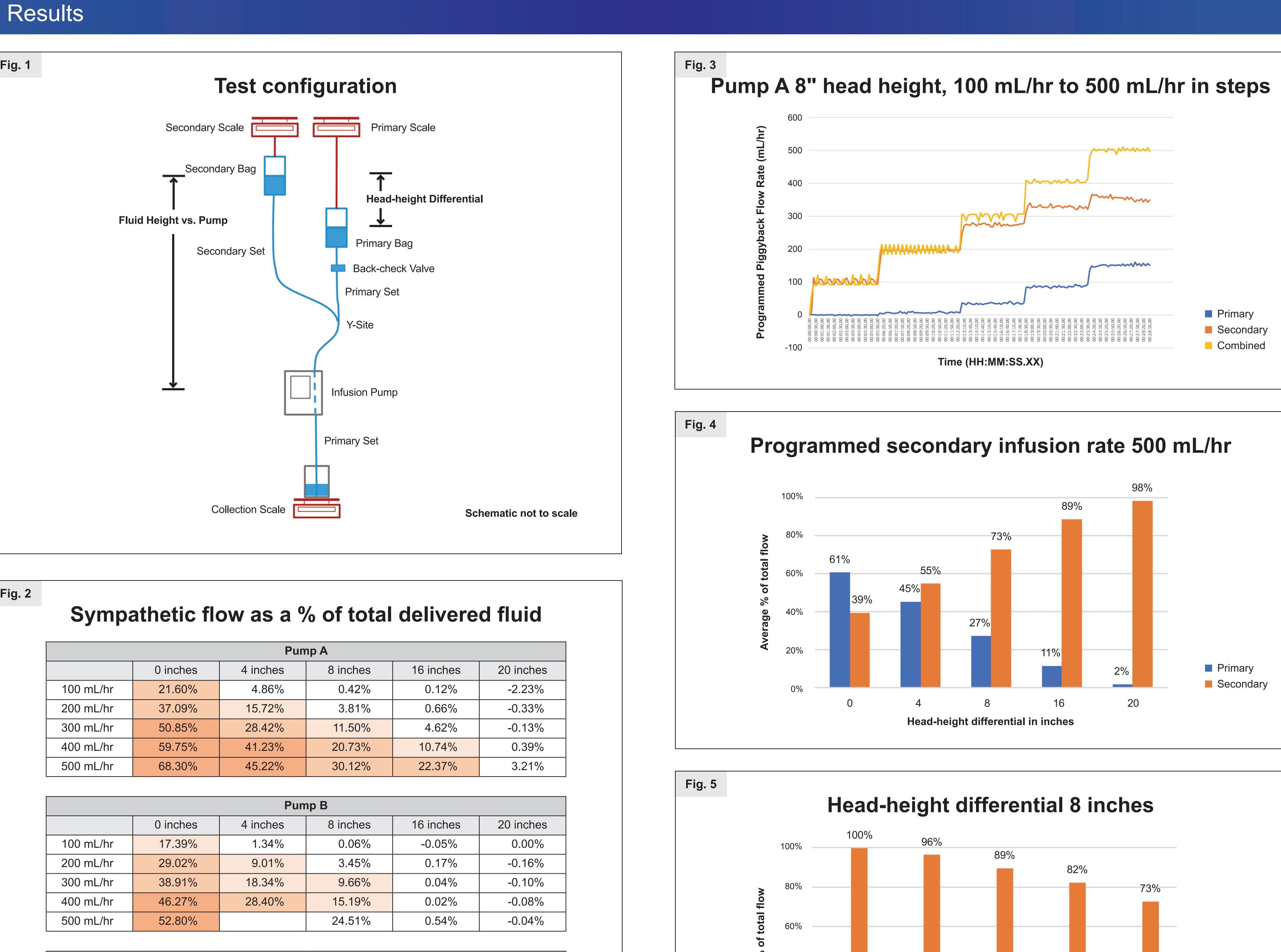


Unintended primary infusion from incomplete closure of administration set back-check valves at various head-height differentials and secondary flow rates

Background Large volume peristaltic infusion pumps deliver secondary Fig. 1 medications, "piggy-back", through the primary administration set • This secondary infusion system requires the use of a backcheck 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^{1,2} 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, air 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 Fig. 2 Methods

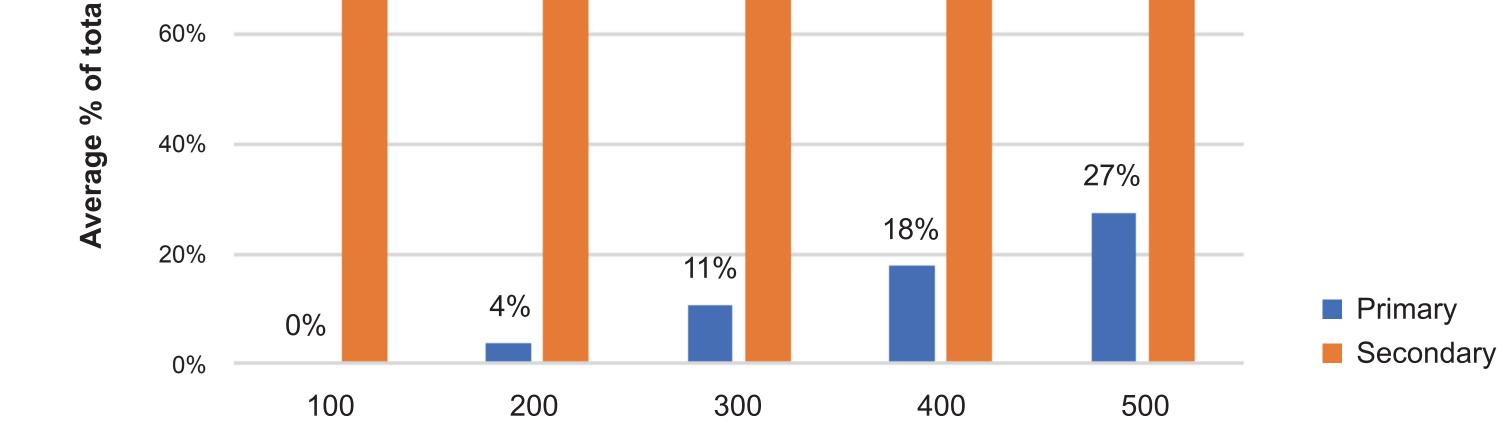
- Two identical, commercially available infusion pumps utilizing administration sets with back-check valves were selected
- The pumps were programmed to deliver secondary infusions at head-height differentials of 0, 4, 8, 16, or 20 inches
- At each head height differential, the secondary infusion was 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 amounts of fluid delivered from the primary, from the secondary, and to the outlet beaker were each recorded continuously per gravimetric methods in IEC-60601-2-24³

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Pump A								
	0 inches	4 inches	8 inches	16 inches	20 inches			
100 mL/hr	21.60%	4.86%	0.42%	0.12%	-2.23%			
200 mL/hr	37.09%	15.72%	3.81%	0.66%	-0.33%			
300 mL/hr	50.85%	28.42%	11.50%	4.62%	-0.13%			
400 mL/hr	59.75%	41.23%	20.73%	10.74%	0.39%			
500 mL/hr	68.30%	45.22%	30.12%	22.37%	3.21%			
	·	•		•	•			
Pump B								
	0 inches	4 inches	8 inches	16 inches	20 inches			
100 mL/hr	17.39%	1.34%	0.06%	-0.05%	0.00%			
200 mL/hr	29.02%	9.01%	3.45%	0.17%	-0.16%			
300 mL/hr	38.91%	18.34%	9.66%	0.04%	-0.10%			
400 mL/hr	46.27%	28.40%	15.19%	0.02%	-0.08%			
500 mL/hr	52.80%		24.51%	0.54%	-0.04%			
Average of Pump A and Pump B								
	0 inches	4 inches	8 inches	16 inches	20 inches			

0 inches	4 inches	8 inches	16 inches	20 inches				
19.50%	3.10%	0.24%	0.04%	-1.12%				
33.05%	12.36%	3.63%	0.41%	-0.25%				
44.88%	23.38%	10.58%	2.33%	-0.11%				
53.01%	34.82%	17.96%	5.38%	0.15%				
60.55%	45.22%	27.31%	11.45%	1.58%				
	19.50% 33.05% 44.88% 53.01%	19.50% 3.10% 33.05% 12.36% 44.88% 23.38% 53.01% 34.82%	19.50% 3.10% 0.24% 33.05% 12.36% 3.63% 44.88% 23.38% 10.58% 53.01% 34.82% 17.96%	19.50% 3.10% 0.24% 0.04% 33.05% 12.36% 3.63% 0.41% 44.88% 23.38% 10.58% 2.33% 53.01% 34.82% 17.96% 5.38%				



Programmed secondary infusion rate mL/hr

CUMECICA human connections

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 headheight 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

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DISCLOSURES

Eric J. Flachbart of Infusion Analytics was paid compensation by ICU Medical to perform and interpret the testing.

Jim Jacobson is an employee and stockholder of ICU Medical.

J.W. Beard is an employee and stockholder of ICU Medical.