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Title: Delivered dose of colistimethate sodium via 3 nebulizers; a comparison of bioassay and HPLC assay results

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Body: In vitro assessment of the dose of inhaled colistimethate sodium (CMS) delivered via a nebulizer has traditionally relied on bioassay (BA). An alternative method is high performance liquid chromatography (HPLC). A custom HPLC assay for CMS has been developed; this is a reversed-phase gradient assay using a 100 x 4.6 mm, 2.6 µm solid core C18 column with UV detection. The HPLC assay was compared with BA using different nebulizers and breathing patterns. Here, results from 3 nebulizers (I-neb AAD System (I-neb), LC Sprint (LCS), LC Plus (LCP)) under 4 breathing patterns are presented. Nebulizers (n=3) were tested using a method described by Byrne et al. (1) Eluate from each filter was analyzed using both BA and HPLC assay.

Table 1: Summary of mean BA and HPLC assay results (MIU) for each nebulizer/breathing pattern combination.

	I-neb		LCS		LCP	
Breathing pattern	BA	HPLC	BA	HPLC	BA	HPLC
A (I:E ratio 1:1, PIF 23.1 L/min, 15 BPM)	0.280	0.277	0.253	0.261	0.291	0.277
B (I:E ratio 1:2, PIF 23.1 L/min, 10 BPM)	0.258	0.264	0.211	0.221	0.207	0.206
C (I:E ratio 1:3, PIF 21.5 L/min, 7 BPM)	0.243	0.258	0.173	0.160	0.161	0.147
D (I:E ratio 1:4, PIF 23.1 L/min, 6 BPM)	0.306	0.270	0.151	0.141	0.155	0.144

I:E ratio=inhalation:exhalation ratio; PIF=peak inspiratory flow rate; BPM=breaths per minute.

The 2 measurement techniques were compared using a Bland-Altman plot. HPLC assay and BA results were consistent; the majority of results fell within 10% of each other (mean difference, 2.8%; limits of agreement, 14.6% to -8.9%). Advantages of the custom HPLC assay include simplicity and speed, whilst yielding results in close agreement with the standard BA. 1) Byrne S, et al. ISAM 2013 abstracts. J Aerosol Med Pulm Drug Deliv.