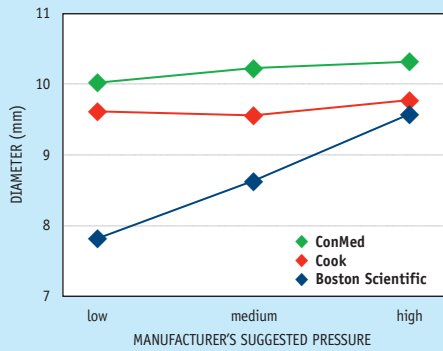


THE ACCURACY OF MULTI-STAGE THROUGH-THE-SCOPE (TTS) ESOPHAGEAL BALLOON DILATORS: DO WE GET WHAT WE PAY FOR?

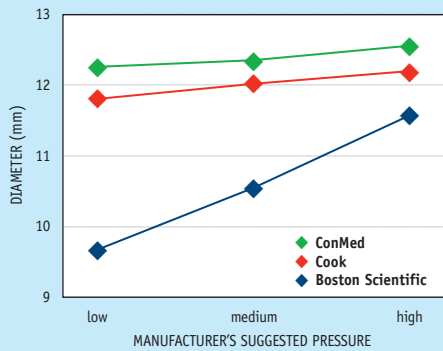
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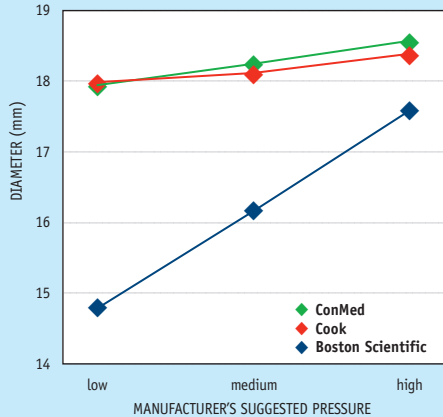
Stage-Specific TTS Balloon Diameters: 10mm Balloons



Stage-Specific TTS Balloon Diameters: 12mm Balloons



Stage-Specific TTS Balloon Diameters: 18mm Balloons



BACKGROUND

Esophageal Multi-stage TTS Dilation Balloons (EMDB) employ varying inflation pressures to achieve a range of target balloon diameters. Typically, there are three stages of inflation with each balloon. The comparative pressure diameter relationship between these EMDB is unknown. Inaccuracies in this pressure-diameter relationship could result in unintended under- or overdilation of an esophageal stricture, with the resultant risks of under treatment or perforation respectively.

AIMS

To determine the pressure-diameter relationships of equivalent EMDB.

METHODS

EMDB with an equivalent diameter range from different manufacturers (Boston Scientific CRE™ Fixed Wire, Boston Scientific, Marlborough, MA; Cook® Quantum TTC®, Cook Medical, Bloomington, IN; ConMed™ Eliminator®, ConMed Corp., Utica, NY) were inflated after immersion for 30 seconds in a water bath at 37°C. Diameters were determined with a laser caliper. Five separate balloons from each manufacturer were inflated for each diameter. The manufacturer recommended pressures were considered as three levels of the same factor (low, medium, high). ANOVA (An Analysis of Variance), was performed (Design Expert 7, Stat-Ease Inc., Minneapolis, MN). This is a test of the statistical significance of the differences among the mean scores of two or more groups on one or more variables.

RESULTS

Results shown for three similar EMDB (Table, Graphs). Though analysis of variance suggests significant diameter differences for each EMDB through its inflation stages, both the Cook Balloon and ConMed Balloon tended to overinflate during the initial stage and exhibited a minimal increase in diameter for the next two stages. For example with the 12mm EMDB, The Boston Scientific CRE™ Balloon tended to have underinflation at each stage but exhibited 96.5% (96.5% = 1.93mm/2mm) of its stated diameter range when compared to Cook (15%). Similar findings were seen with the 10mm and 18mm CRE and Cook Balloons as well. For the ConMed Balloon, the change in diameter from the low to high pressure was 0.28mm for the 12mm balloon. The corresponding % change in the stated diameter range can not be determined as ConMed does not provide sizes with the stated multistage pressures in the DFU.

CONCLUSIONS

Clinically important pressure-diameter EMDB characteristics have been identified including overinflation and limited inflation diameter range. These should be taken into account when performing esophageal stricture dilation.

Adaptation from DDW 2007 Poster S1274. All trademarks are the property of their respective owners. Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Stage-Specific TTS Balloon Diameters

Max. Nominal Diameter	Manufacturer	Mean Diameter at Recommended Pressure Level (mm)			Actual Inflation range (mm)	Regression Equation	P value for the regression
		Low	Medium	High			
10mm Balloons	Boston Scientific	7.8	8.66	9.63	1.83	$6.926 \pm 0.3037 \times \text{Pressure}$	0.039
	Cook	9.69	9.63	9.73	0.04	$9.62 \pm 0.0133 \times \text{Pressure}$	0.740
	ConMed	10.09	10.2	10.29	0.20	$9.90 \pm 0.0640 \times \text{Pressure}$	0.037
12mm Balloons	Boston Scientific	9.65	10.55	11.58	1.93	$8.55 \pm 0.383 \times \text{Pressure}$	0.048
	Cook	11.86	12.03	12.16	0.30	$11.6 \pm 0.107 \times \text{Pressure}$	0.002
	ConMed	12.32	12.41	12.6	0.28	$12.0 \pm 0.0913 \times \text{Pressure}$	0.129
18mm Balloons	Boston Scientific	14.84	16.17	17.59	2.75	$12.94 \pm 0.6753 \times \text{Pressure}$	0.079
	Cook	17.99	18.14	18.27	0.28	$17.70 \pm 0.1643 \times \text{Pressure}$	0.048
	ConMed	17.93	18.26	18.44	0.51	$17.44 \pm 0.3014 \times \text{Pressure}$	0.085

Bench data on file and will be made available upon request.