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TECHNICAL PERFORMANCE OF THE T-DOC® AIR-CHARGED CATHETERS – AN ALTERNATIVE TECHNOLOGY FOR URODYNAMIC STUDIES

Hypothesis / aims of study

Urodynamics (UDS) is frequently used to assist in the diagnosis of lower urinary tract dysfunction. Air-charged catheters (ACC) are amongst the available technologies to perform UDS and have been widely used for the past 15 years [1]. Frequency response, pressure drift over time, as well as linearity and hysteresis are important characteristics when considering accuracy and precision for a catheter-manometer system [1,2]. The aim of this study was to assess the ACC performance for these 3 aspects utilizing laboratory controlled settings.

Study design, materials and methods

A total of 180 T-DOC® ACC were used in 3 different laboratory settings to assess pressure linearity & hysteresis (15 dual-sensor and 30 single-sensor abdominal), pressure drift over 2 hours (115 single-sensor), and frequency response (20 dual-sensor, only vesical sensor assessed). For that, customized chambers were used to control and monitor the pressures. Frequency response tests had the peak values for the ACC normalized to the peak values of the system reference to compensate for inherent variation of the water test chamber. Response of the ACC was characterized by identifying the frequency at which the reference signal was attenuated by 50%. Microsoft Excel and Sigma Plot were used to analyse the data recorded. Data is presented as mean ± standard deviation, significant difference was considered when $p < 0.05$.

Results

ACC showed linearity of 0.99 ± 0.01, 0.99 ± 0.01, and 1.01 ± 0.01; and hysteresis of 0.57 ± 0.3%, 0.76 ± 0.48%, and 1 ± 0.89% for the vesical, urethral, and abdominal sensors respectively. The absolute pressure was 43.74 ± 1.45 cmH2O at baseline, 42.71 ± 1.41 cmH2O at 1hr, and 41.69 ± 1.85 cmH2O at 2hr. A slow pressure drift was observed in all bladder ACCs with a reduction in the measured pressure by 2.3 ± 1.7% at 1hr and 4.6 ± 3.4% at 2hr when compared to the baseline pressure. The ACC did not have any amplification factor during the sweep from 1 to 30 Hz. The catheters had a signal attenuation higher than 50% when the frequency measured was 5Hz or above. No signal amplification was observed on the frequency response test.

Interpretation of results

Values of ± 1% over a range of 0-100 cm H2O are generally considered acceptable for hysteresis [2]. This study showed that the pressure exerted from the body cavities to the ACC will demonstrate acceptable linear behaviour and also that, fluctuations in cavity pressure will not lead to deviation in true pressure during UDS. The ACC showed a pressure drift of less than 5% over 2 hours, and expected duration of a regular UDS study is less than 60 minutes. Previous studies showed that frequency response should be at least 3Hz for transducers, as most pressure signal changes in UDS occur under 3Hz [1], and that 88% of the power spectrum of coughs are below 3Hz [3]. This study established a cut-off of 5Hz which should be adequate to capture most of the clinically relevant pressure events during UDS [1].

Concluding message

The linear performance with minimal hysteresis associated, satisfactory pressure drift, along with acceptable frequency response to capture clinically relevant pressures, suggest these catheters are suitable for use in UDS studies. Further studies are needed to characterize different features of the ACC.

References

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