

PROOF OF PRINCIPLE FOR A NON-MANUAL CATHETER VALVE; VOIDING AND STORAGE FUNCTION USING A VALVE OPENED BY VOLUNTARY STRAINING

Hypothesis / aims of study

Development of a catheter valve that does not require manual dexterity is an area of need, since indwelling catheters may be needed in people who are unable to open a conventional catheter valve. We hypothesised that Valsalva straining can serve to initiate flow along a catheter and valve without manual activation.

Vysera Biomedical has developed novel biomaterials that can mimic the mechanical properties of soft biological tissues and are demonstrated biocompatible, biostable in urine, resistant to encrustation and can be sterilised easily. A trifoliate valve design was developed, whose function is to remain closed during short duration pressure spikes (e.g. cough), and to open automatically with a more sustained pressure increase (strain). Such a valve does not require the individual to have manual dexterity, as the valve is opened by the application of abdominal strain and closes again automatically once flow has ceased. Valve performance was designed such that its dynamic response was both time and pressure dependent. This feature allows for the desirable ability of the valve to remain closed during short, high amplitude pressure peaks (representative of the time-pressure characteristic generated during cough) while also allowing the valve to open when a pre-defined steady state pressure is applied for a pre-defined longer period of time (typical of Valsalva strains). The specifications can be adjusted during manufacture, to vary the "break-point" (when the valve opens and allows flow), in terms of absolute pressure and duration.

The aims of the study were to identify specifications required, and to test performance *in vitro* and *in vivo*. We wished to confirm that people can initiate bladder emptying voluntarily by straining, that leakage does not happen during routine physical activity, and that the valved catheter is well tolerated during storage and emptying.

Study design, materials and methods

1. **PRESSURE SPECIFICATIONS;** The likely range of pressures encountered *in vivo* at rest, and during coughs and strains were measured from a urodynamic database [1].

2. **IN VITRO TESTING** The designed valve was placed in a polycarbonate housing, and inserted in a Foley catheter whose proximal end was located in a pressurised vessel containing water at 37C. The pressure within the vessel was controlled with an electronic pressure regulator (SMC Pneumatics ITV1010-311BL5-X323) driven with a customised signal generator (Vysera) capable of generating steady state and dynamic pressure patterns between 5 and 70cmH₂O and with impulse and rise times between 0.1s and 99.99s, with a resolution of 0.01s. Applied pressure was measured using an electronic transducer (Sensortech SSIM700GU9AH5) located adjacent to the device.

3. **IN VIVO PROOF OF PRINCIPLE TESTING IN HUMAN** using a prototype valve. Seven patients with chronic indwelling catheters were invited to attend the department for a period of up to 8 hours. The valve was placed in the catheter and at least two natural filling and emptying cycles were undertaken. A standardised schedule of position changes, ambulation and coughs of increasing severity were undertaken. A device usage questionnaire was administered (ten questions, rated on a scale from 1 to 5 with 1 = very poor, 2 = less than acceptable, 3 = acceptable, 4 = good, 5 = very good). Participants were also able to give any additional comments they wished to. Urodynamic measurements were taken from the catheter using a water-filled system, with the reference height taken from the symphysis pubis. The study was approved by the regional ethics committee, and the valve was approved by the UK Medicines and Healthcare Regulatory Agency (MHRA).

Results

PRESSURE SPECIFICATIONS; Resting pressures of up to 44 cmH₂O were seen for sustained durations [1]. Pressure spikes (coughing) of up to 76 cmH₂O were up to 0.5 seconds duration. Median strain pressure achieved by patients was 75 cmH₂O.

Accordingly, the specification for the valve opening was initially set at the median strain pressure of 75 cmH₂O, sustained for more than 0.5 seconds duration. The strain pressure achieved by some patients was below the maximum resting pressure observed; such patients are unlikely to be suitable for this type of valve.

IN VITRO TESTING Valves manufactured could specify opening pressures between 20 and 350cm H₂O (opening pressure defined as the pressure required to open the valve with the specified pressure applied for a period of between 5 and 10 seconds). These valves had a cough withstand factor of 20% above the opening pressures, with a cough duration of 0.5s and a 0.5s delay between coughs.

Based on the urodynamics database analysis carried out initially, valves were selected with nominal opening pressure of 75cmH₂O and a range of +/-15cmH₂O (range 60-90cmH₂O).

IN VIVO TESTING; Upon verification of the physiological pressures measured at the tip of the Foley catheter in 7 patients, it was evident that the valves selected should have a high opening pressure (up to 230cmH₂O) and cough withstand factor (of the order of 40-70%). In general, male patients generated strain and cough pressures 2-3x that of female patients and pressures did not relate to body mass index. Six of the seven patients (86%) were able to open the valve by straining. The one who could not suffered from MS and could only generate very low strain pressures and only for a relatively short time. No patients experienced leakage during the store & fill cycle while static (7/7=100%). Five patients (5/7=71%) experienced leakage when they coughed. Of these five, two experienced leakage only when the cough was very aggressive (a "choking" cough). Two patients (2/7=28%) experienced no leakage even with choking coughs. 2/7=28% experienced leakage due to events other than coughing e.g. changing from lying to sitting/ sitting to standing, or moving positions while lying or sitting. There were no complications. Summary features of the patient questionnaire are tabulated:

	Patient 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	MEAN
Overall impression of device	5	5	4	4	4	5	5	4.57 (0.53)
Ease of use	5	5	4	4	5	5	5	4.71 (0.49)
Speed of bladder emptying with device	5	5	5	5	3	5	4	4.57 (0.79)
Bladder comfort after emptying using device	5	5	4	4	5	5	3	4.43 (0.79)
Did bladder feel empty?	5	5	4	4	4	5	3	4.29 (0.76)

Outliers & Observations; Females generated maximum strain pressure in the sitting position, whereas males generated it in the standing position. One male patient with chronic obstructive pulmonary disease had very high strain pressures (>190cmH₂O) which were equal to or higher than his cough pressures. His breathing caused oscillation of +/-10cmH₂O around resting pressure. One patient with MS had very low maximum strain pressure of 65cmH₂O and was able to apply this for no more than 6 seconds. Patient comments; One patient commented that the large choking cough that she applied and which opened the valve was “unnatural” and would only have been used if she was trying to recover from a choking episode. She would have leaked from such a cough – even before she was diagnosed as incontinent. Patient 1 stated “I think the device is brilliant...”

Interpretation of results

The valve design appears feasible for use by patients, and is well tolerated. Most patients can open the valve and achieve bladder emptying. Valve performance was affected by the higher pressures evident when the pressure was measured at the end of a Foley catheter versus that measured using conventional cystometry. This could not be assessed during the initial pressure specification phase of the research, since the latter only employed cystometry. Therefore, the pressure difference (which is what activates the valve) was found to need an additional correction during *in vivo* testing. It is likely that valves used in clinical practice will require urodynamic parameters for individual selection of specifications.

Concluding message

Voiding and storage using a strain-activated non-manual catheter valve is feasible and well-tolerated. Additional development is needed to refine valve specifications, and in clinical practice valve parameters will need to be matched to individual patients.

References

1. Hogan S, Gammie A, Abrams P. Urodynamic features and artefacts. *Neurourol Urodyn.* 2012;31:1104-17.

Disclosures

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