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REVIEW ARTICLE

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Air filled, including "air-charged," catheters in urodynamic studies: does the evidence justify their use?

Paul Abrams[1]* | Margot S. Damaser[2,3] | Philip Niblett[4] | Peter F.W.M. Rosier[5] | Philip Toozs-Hobson[6] | Gordon Hosker[7] | Robert Kightley[8] | Andrew Gammie[1]

[1] Bristol Urological Institute, Southmead Hospital, Bristol, UK

[2] Department of Biomed Engineering, Cleveland Clinic, Cleveland, Ohio

[3] Research Service, Louis Stokes Cleveland Veterans Administration Medical Center, Cleveland, Ohio

[4] Exeter Scientific Developments, Exeter, UK

[5] University Medical Centre Utrecht, Heidelberglaan, Utrecht, The Netherlands

[6] Birmingham Women's NHS Foundation Trust, Birmingham, West Midlands, UK

[7] (Retired) The Warrell Unit, St Marys Hospital, Manchester, UK

[8] Department of Medical Physics and Biomedical Engineering, University College London Hospitals NHS Foundation Trust, London, UK

***Correspondence**
Paul Abrams, Bristol Urological Institute, Southmead Hospital, Bristol BS10 5NB, UK.
Email: paul.abrams@bui.ac.uk

AIMS: Air filled catheters (AFCs) have been actively marketed for the past few years and in some geographic areas are widely used. However, as the scientific basis for introduction of this technology for pressure measurement in urodynamics was not clear, a study group examined the evidence.
METHODS: A search of the peer reviewed literature was carried out.
RESULTS: Four papers were identified, of which two were laboratory experiments and two were clinical papers, in female patients, that compared the pressures recorded by AFCs and those recorded using the traditional water filled catheters (WFCs). These data show that there are differences between the pressures measured by the two types of catheters. As yet, the reasons for these differences are not clear.
CONCLUSIONS: There should be further systematic laboratory and clinical research before AFCs can be recommended for routine clinical use. We would recommend that a professional worldwide multidisciplinary scientific society, such as the International Continence Society, should work with manufacturers and regulatory bodies to ensure that this urodynamic method is properly scientifically evaluated, in the wider interests of patient safety.

KEYWORDS
air-filled, pressure measurement, urodynamics, water-filled

1 | INTRODUCTION

Air filled catheters (AFCs) in urodynamic studies (UDS) were introduced in the 1970s by Douglas James, a medical physicist working in Exeter, UK, and both single and twin channel pressure catheters have been described. Dr James took the view that UDS should be done in as physiological a manner as possible. At that time conventional UDS, using water filled catheters (WFCs), was performed in only two or three centers in the UK and followed a methodology that is broadly similar to that used today. In what has become conventional UDS, the patient is connected to the recording equipment by WFCs and water-filled manometer tubing. The main limitations of the WFC system is that patient movement causes high frequency artifactual signals that are transmitted to the transducer by the water column, and as a result make the urodynamic traces harder to interpret. Furthermore, in conventional UDS, the external pressure transducers are, by convention levelled to the symphysis pubis (see below), and atmospheric pressure is taken as the standardized zero. Therefore, when the patient moves, the bladder and rectum are then either below or above the recording transducers, and re-levelling of the transducers is required. In order to overcome these problems, Dr James developed and used catheters that were filled with air and which terminated with a small compliant micro-balloon. AFCs overcome the problem of artifact during patient movement, seen in WFC systems, since the low mass and high compliance of air prevents these artifacts being generated or transmitted. Hence, the patients he investigated in Exeter were able to move more

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freely around the urodynamic laboratory and to perform a wide range of provocation exercises during UDS, particularly to demonstrate exercise-induced stress urinary incontinence and detrusor overactivity. Dr James published the background to his methodology during the late 1970s.[1,2] This not only described the advantages of AFCs during ambulant UDS, but also described the advantages of concurrently using an electronic perineal pad which approximately quantified the volume, but more importantly the timing, of urine losses and their relationship with urodynamic pressure changes.[3,4] The Exeter methodology has continued to this day; however, the technology has only been routinely used in the Department of Clinical Measurement in Exeter and in the UDS clinic at North Devon District Hospital.

In 1998, the T-Doc system was introduced. For many years it was little used. However, in the last few years it has been marketed by several urodynamic manufacturers as part of their urodynamic package with their own machinery. The T-Doc system was invented by Clinical Innovation Associates, Inc., who filed the US patent 6 447 462 in the year 2000, and the system is now owned and marketed by Laborie, a urodynamic equipment manufacturer. These systems are sold under license largely through other urodynamic manufacturers.

Urodynamic studies should be performed according to the International Continence Society (ICS) Good Urodynamic Practices report of 2002,[5] usually to confirm clinical diagnoses prior to the use of invasive therapies to treat lower urinary tract dysfunction. The principal storage phase abnormalities identified during filling cystometry are reduced compliance, detrusor overactivity (DO), which may be the cause of bothersome overactive bladder symptoms, and urodynamic stress incontinence (USI). During a pressure flow study, the principal abnormalities found are bladder outflow obstruction (BOO) characterized by high pressure and low flow, and detrusor underactivity (DU) characterized by low flow and low pressure. The diagnoses of DO and USI during filling do not require precise pressure measurements and are judged by the pressure change pattern and the detection of urinary leakage in the presence or absence of a detrusor contraction, respectively. However, precise, valid, and reproducible pressure measurements are important in several aspects of UDS:

- In research studies, on new compounds, such as those that aim to treat DO, precise measurements are made, for example, the maximum pressure during any DO contraction, at baseline and at endpoint whilst the patient is on drug or placebo. Similarly, precise pressure measurements are required in order to calculate bladder compliance, often seen in neurogenic patients.
- The assessment of urethral function, by urethral pressure profilometry and by leak point pressures, is used to plan surgical treatment of USI and the precise pressure measurements are used to define intrinsic sphincter deficiency.
- The diagnosis and grading of BOO in both men and women, but particularly in older men being considered for surgery for possible benign prostatic obstruction, depends on the precise value of detrusor pressure and specifically its value at the point of maximum flow.
- Similarly, the diagnosis and quantification of DU, a voiding phase abnormality that is currently attracting renewed interest, requires precise pressure measurement for diagnosis.

The quantification and definitions of these conditions, including cut-off values, have been developed exclusively using WFCs, but to date there are no equivalent data for AFCs. Hence, it is vital that the relationship between pressures recorded with WFCs and AFCs is scientifically robust, and in regions where AFCs are in widespread use, the need for data is especially urgent.

This paper results from a meeting held in June 2015 between clinicians and clinical scientists known to have used, studied and/or published on the use of AFCs. Scientists from several countries participated, some by internet link. The authors felt that there should be a review of both the technical fundamentals and the published evidence to establish whether it supported the applicability of AFCs to clinical practice. This paper aims to assess the peer reviewed published data, and the non-peer reviewed available data, on AFCs used during standard UDS. The ICS standard for cystometry and pressure-flow with WFCs and external pressure transducers levelled to the symphysis pubis for both intravesical and abdominal pressure measurement was used as the reference.[5]

This paper does not include a discussion of the use of WFCs or AFCs during urethral function studies.

2 | METHODOLOGY

Pubmed and other databases were searched using the terms “air filled catheters” and “air charged catheters”. In addition, known authors were searched through Pubmed and Google Scholar. Websites of urodynamic manufacturers were also searched for additional information. All papers were then recovered, examined, and studied in detail.

2.1 | Terminology

The term AFC is the original term used in the literature and is a scientifically appropriate description. The term “air charged catheter”® refers only to the T-Doc system and is a protected trade mark. It is appropriate in the scientific literature to use a generic terms, hence, the term AFC will be used throughout this paper.

The term WFC is used as the generic term for the water-filled external pressure sensor systems used for the last 50 years in ICS standard UDS.

2.2 | Principles of physiological measurement

The UK's National Physical Laboratory states six guiding principles of measurement in general,[6] which can be summarized as: make the right measurement; choose the right instruments; the right people; regular review; demonstrable consistency; and the right measurement procedures.

These principles underline the concepts that measurement technologies must follow in the description of their accuracy, applications, procedures for use, and repeatability, all backed up by data. Also, users need to be aware of limitations and the possibility of artifacts, in order to make proper adjustment or interpretation. The Laboratory goes on to say that since some error is inevitably present in any measurement, clear data must be available and be understood in order to recognize the level of confidence that can be expected.

2.3 | Theoretical aspects of measurement with WFCs and AFCs

WFCs use a continuous water column from the body cavity (bladder or rectum/vagina) to the external pressure transducer that is zeroed to atmospheric pressure and sited at the level of the upper border of the symphysis pubis of the patient. Both the intravesical and abdominal pressure, usually measured in the rectum, are therefore, defined as the excess pressure above atmospheric pressure at the hydrostatic level of the upper edge of the symphysis pubis.

AFCs use an air channel in the catheter that is closed to the patient, connected to a transducer, and also zeroed to surrounding atmospheric pressure before insertion. Although air is also a fluid, the hydrostatic difference between the catheter tip, when in the bladder, and the transducer is considered negligible, because the weight of a column of air is negligible. Also even though air is easily compressible and might result in damping of the pressures, whereas water is not, it appears to matter only in the range of urodynamics pressures which rapidly change over a large amplitude, for example, during a cough or during brisk physical activity such as running or jumping on the spot when using AFCs. Contrary to the WFCs, the AFCs effectively register the pressure at the tip of the catheter. As long as the definition of pressure is the excess pressure above the symphysis level, AFC pressure, measured in the balloon near the tip of the catheter located at a position inside the body, that is not exactly known, cannot technically meet that definition. The pressure readings at the height of the balloon may, therefore, differ by several cmH_2O from the pressure at the level of the symphysis pubis, and may be clinically important.

It is also unknown how and whether the pressure measuring balloons of the catheters stay in position, both with respect to the patient and with respect to each other, under the influence of bladder filling and patient movements.

2.4 | Technical aspects of pressure measurement using AFCs

AFCs can be viewed as simple devices which transmit the pressure within an air filled micro-balloon to an extra-corporeal pressure transducer, without any acceleration or pressure artifacts relating to patient/catheter movement. The operational characteristics of AFCs are not just confined to urodynamic studies, but have also been used, for example, in esophageal and respiratory pressure measurement. AFCs are, however, quite complex and can be easily misunderstood. There are numerous factors that could theoretically affect the performance of an AFC system, making the design of such a system crucial, depending on the physiological measurement application:

(a) Ideally the pressure inside the micro-balloon should always be equal to the pressure outside the balloon (the pressure we require to measure). This will depend on the compliance of the balloon. Changes in compliance as the micro-balloon changes in shape and or volume may, therefore, cause errors in the measured pressure.

(b) The micro-balloon must be primed with air to a partially inflated state so that, as the air in the balloon warms up to body temperature, the increase in volume is accommodated without any change in balloon pressure. The reliability of measurement is affected especially when the charging overfills the balloon.

(c) The amount the micro-balloon deflates as the measured pressure rises depends on the ratio of the volume of air within the balloon compared with the volume of air within the catheter tubing, luer connection, and pressure transducer. For this reason, the volume of air within the tubing, connection, and transducer has to be carefully minimized in order to ensure that the AFC can respond to the highest required urodynamic pressures of 250 cmH_2O. The lack of commercially available low internal volume medical grade pressure transducers suitable for connection to the AFCs introduced by Dr James has, we understand, been one of the primary stumbling blocks in promoting/scientifically evaluating the Exeter AFCs in a wider context.[7]

(d) The frequency response of the AFC system is significantly controlled by the length and internal diameter of the catheter, reducing roughly proportional to the catheter length and fourth power of the internal diameter, due to the compressibility of air. For very small internal diameters,

the frequency response is not only very low but also overdamped, but as the diameters increase the AFC will become more critically damped, or even under-damped as well as demonstrate an increase in frequency response.[8]

(e) The catheter should be sufficiently flexible to prevent any significant artifactual pressures being generated within the balloon if it became pressed against the bladder/vaginal/rectal wall.

(f) The catheter and associated transducer should exhibit minimal air-leakage over the measurement period so that the capability of measuring up to maximum specified pressures (250 cmH_2O) is maintained.

Overall there is a critical trade-off between the size/volume of the micro-balloon, catheter/transducer internal volume, and frequency response, such that if a small balloon is employed (as in the T-Doc catheters), the bandwidth by necessity will be low, approximating to a maximum of 3 Hz.[9] Employing the larger micro-balloon of the Exeter system allows a much higher bandwidth (typically up to 14–28 Hz) which is more suited to the ambulatory urodynamic procedure for which it was designed.

The Exeter AFC (Malvern Medical Group, Worcester, UK) is standardized to 60 cm for both male and female use, with a constant internal diameter of nominally 0.56 mm and with balloons of typically 5–6 mm diameter and maximum length of 19 mm. The bandwidth is typically up to 27 Hz, dependent on catheter length.[9] Unlike the T-Doc catheter, the Exeter balloon catheter is partially inflated and zeroed to atmospheric pressure before catheterization to ensure no pressure offset errors. The catheter tubing is made from flexible, but thick walled PVC (2.1 mm diameter), to ensure minimal transmission of forces from the catheter to the balloon, to provide a more comfortable catheterization process and to ensure minimal pressures are exerted on any surrounding tissues. The balloons are batch calibrated, and identical AFCs are used for bladder, vaginal, and rectal pressure measurements. The critical maximum frequency response of the T-Doc is approximately 3 Hz[9] and this is too low to capture the most rapid changes in pressure, such as during coughs and cough leak point pressure measurement.[10] The suggestion that bandwidths of up to 14–15 Hz are required to accurately reproduce rapidly changing urodynamic pressures has been endorsed by both the earlier[11] and the latest[12] ICS Guidelines on Urodynamic Equipment Performance. The Exeter AFCs have to date only been manufactured for use by the Exeter and North Devon group, but the manufacturer now reports it is exploring a wider commercial base for development of the catheter, once the necessary technical performance data is available.[7] No comparable design data for the T-Doc AFCs has been found, but their external size is given as 7 Fr (i.e., 2.3 mm diameter).

In our view, technical performance data, clinical data, and comparative data with the standard should be provided, that is, in the public domain, before any air-filled device is actively marketed on a wide platform. At present, this is neither available for the Exeter nor the T-Doc catheters. The use of microtip electronic transducer catheters as the gold standard in in vitro studies makes sense since there is no medium through which the pressure has to be transmitted. However, in patient studies, microtip electronic transducer catheters are rarely used and comparison with WFCs is more appropriate, as only WFC systems measure pressure at a known level in the patient.

2.5 | Comparison of WFCs and AFCs

Two studies of the performance of T-Doc AFCs in vitro have been published in the peer-reviewed literature to date. These focus on their frequency response, since air dampens dynamic changes in pressure (e.g., signals from coughs, movement), and thus can be considered an over-damped system. In contrast, water is an underdamped pressure transduction medium and as a result, has a resonant frequency at which some pressure changes are magnified. Cooper et al. tested both AFCs and WFCs, placed simultaneously in a pressure chamber, using standard engineering tests such as a transient step test and a frequency sweep test.[13] These tests demonstrated that T-Doc AFCs act as a low-pass filter with a cut-off point at 3 Hz. In contrast, WFCs are a second order underdamped system and as such, have a broad resonance frequency of approximately 10 Hz, amplifying the signal from frequencies approximately 5 Hz to approximately 15 Hz and attenuating signals above 15 Hz.[13]

These alterations of the pressure signal by the pressure transduction system only matter to clinical urodynamic testing if the frequencies at which they occur are significantly represented in clinical urodynamic pressure signals. Cough tests are generally considered to generate the fastest changing (i.e., highest frequency) intravesical pressure signal in UDS testing. Therefore, Thind et al. assessed the frequency spectrum of cough tests in six healthy volunteers: four men and two women.[14] They found that 99% of the power of the bladder pressure signal in a cough occurs at frequencies of 9 Hz or less. In an analysis of 131 consecutive pairs of urodynamic measurements during voiding, Kranse and van Mastrigt report that most of the signal power occurred at frequencies less than 1 Hz.[15] This suggests that AFCs are capable of recording bladder pressures during voiding accurately, but that T-Doc AFCs will likely attenuate the bladder pressure (i.e., record a lower bladder pressure than actual pressure) during coughing, since coughs cause a much faster rise in bladder pressure than voiding. WFCs can likewise record bladder pressures during voiding accurately, but in contrast to AFCs, can potentially amplify the bladder pressure during cough tests.[10,13]

As a further step, Awada et al. simultaneously tested T-Doc AFC and WFC pressure measurement systems in a pressure chamber with pressure signals consisting of systematic variations on bladder pressures during coughs and Valsalva manoeuvres.[10] AFCs underestimated the WFC pressure of events lasting less than 0.5 s, consisting primarily of coughs, which last approximately 0.2–0.25 s. In contrast, Valsalva manoeuvres result in an increase in bladder pressure that lasts 1–2 s. Awada et al. developed an algorithm to convert bladder pressure during cough and Valsalva tests, collected using T-Doc AFCs, to the maximum pressure that would have been recorded had a WFC been utilized. The algorithm was able to correct 90% of maximum pressures measured by T-Doc AFCs to within 5% of those measured simultaneously by WFCs. Since the algorithm is meant only to correct maximum pressures, it does not restore any artifact due to movement, the lack of which is a key advantage of the AFCs over WFCs. In addition, the algorithm ought to be validated with in vivo studies since other factors, such as tissue-catheter interaction, are at play clinically that are not present in the highly controllable pressure chamber experiments from which the algorithm was derived.

Digesu et al. measured in vivo urodynamic pressures simultaneously with T-Doc AFCs and WFCs during the start of bladder filling, the end of filling, on standing, on sitting prior to voiding, and at maximum (overactive) detrusor contraction during storage.[16] The hypothesis was that both pressure systems were recording equal values; however, Digesu et al. found that AFCs recorded higher pressures than WFCs.

Since the experiments of Awada et al. were benchtop studies that precisely characterized the two pressure measurement systems, including properties of both media and tubing, the results reported by Digesu et al., must be from interaction of the catheter systems with the pelvic organs in vivo. This is highlighted by their result that the difference between the two catheter systems was greater in the rectum than in the bladder, suggesting a physiological, rather than physical reason for their results. The position of the AFCs within the patient may have generated some different values, but this was tested and rejected by Gammie et al. (see below). It could also be that WFCs have some error in recording the pressure in an empty bladder, which will need further investigation, yet the recorded pressures remained different throughout the UDS. This nevertheless engenders additional questions such as: could these differences be minimized with different catheter placement or other? Could the catheters be adapted to accommodate rectal mucosal interference or pressure by the rectal wall on the catheter balloon, if that is found to be the source of the pressure difference?[17]

In another in vivo study in female patients, Gammie et al.[18] compared pressure readings obtained from T-Doc AFC and WFC with respect to their values at the beginning of the test, since that is what is done in clinical practice. Even with the starting values taken into account, they reported 95% limits of agreement between the two of +/− 10 cmH_2O. Gammie et al. checked the pressure readings on each system in vitro after each urodynamic test and found the static pressures reliably agreed to within 2 cmH_2O at a static test pressure (which enquiry revealed to be 30 cmH_2O), indicating, as in the Digesu et al. study, that the difference in readings was due to insertion into the body, not the medium of pressure transmission. It should be understood that the Bland–Altman comparison method used,[19] describes differences between two methods, rather than being a comment on the absolute accuracy of either. However, WFCs are the better validated of the two methods, in the sense that there is far more research data using WFCs than AFCs. On these grounds, Valentini and Nelson have stated that AFCs "have not demonstrated their reliability in vivo."[20]

McKinney et al. reported, though only on the Laborie website and related conference abstracts, a study with 25 women, measuring pressure using a T-Doc AFC balloon catheter while also using the filling line of the same catheter as a WFC.[21] This had the advantage of ensuring that no WFC in the bladder could interfere with the AFC balloon. The results were only given for cough and Valsalva maximum pressures, not steady state pressures, and only considered p_{ves}. Thus, the conclusion from these observations that "Cystometric pressures measured using air-charged catheters are comparable with water-filled catheters" is not justified, as all cystometric pressures are not compared. Results indicated good correlation between AFC and WFC values over the p_{ves} pressure ranges measured, with better agreement for Valsalvas on fuller bladders. The actual range of differences between the systems appears, from the Bland–Altman chart included, to be between −6 and +17 cmH_2O. This latter value, rather than the correlation, will be of more interest to clinicians, as it will indicate the likely accuracy of any given pressure measurement, and it is of the same order as differences reported by both Digesu et al. and Gammie et al.

An earlier, exploratory study[22] of the T Doc AFC system was carried out in a small number of eight female patients and looked at the data from simultaneous measurement of pressures using AFCs (zeroed to atmosphere) and WFCs (according to ICS standards[5]). Recorded pressures were sampled at the start of the filling, at maximum cystometric capacity, on standing and with coughing to give fixed reference points. The researchers concluded that there was good inter-observer agreement and although the intravesical measurements, between AFCs and WFCs, correlated well, the differences represented too great a difference in clinical terms. The correlation between abdominal pressures was weak with insufficient agreement. In addition, there were some patients who developed urethral soreness and hematuria, presumed to be due to friction within the bladder from the stiffness of the catheter. However, later, the manufacturer

made a change in the instructions for use; the T-Doc catheters are now only recommended to be used for up to 1 h routinely without recharging.[23] This means that they are inappropriate for longer ambulatory monitoring, even though one conference abstract had reported no significant change in response over 4 h.[24]

2.6 | Clinical experience of using AFCs

The use of AFCs in Exeter has been discussed above. Further experience comes from another center which has used the T-Doc AFC system for 7 years, since 2008, having previously used both Gaeltec micro-tip catheter for intravesical (and intra-urethral) pressure measurements and a homemade air-filled balloon (about 6 cm long and 1.5 cm diameter when inflated with 20 ml air) to measure abdominal pressure rectally.[25] However, although the intravesical T-Doc AFC is used to measure bladder pressure, it is also used to measure abdominal pressure rectally rather than use the rectal T-Doc AFC with its stiff, integral guide wire. Previous experience, with anal manometry, had shown that because the rectal T-Doc AFC was stiffer, it was sometimes harder to introduce into rectum than the intravesical T-Doc AFC. The tip of the former, with its stiff guide wire, appeared to "snag" on the walls of the anal canal and cause patient discomfort during insertion. The use of an intravesical T-Doc AFC for measuring abdominal pressure continues, although it is now used vaginally rather than rectally because there had been some problems "balancing" the traces, which appears to have solved this problem. Very occasionally, a large pressure rise was seen, when charging the AFC from its "zero" status and this was attributed to some manufacturing problem and remedied by changing the catheter. AFCs have not been used for measuring pressure during "fast" events such as coughing, for example, during cough leak point pressure as intuitively it was not expected to have a satisfactory response time. However, under cystometric examination, not requiring a fast response, AFCs were considered to be a practical and easy way of carrying out UDS.

3 | DISCUSSION

3.1 | Regulatory aspects in EU and FDA

In the USA, the Food and Drug Administration (FDA), Code of Federal Regulations Title 21, Volume 8 (21CFR876.1620) defines a UDS measurement system. UDS measurement systems are classified as Class II (special controls) by the FDA and as such the device is exempt from the premarket notification procedure and can be approved by the FDA's 510(k) process. Since the AFC is a component of such a UDS measurement system, it presumably falls under this classification. Under EU legislation, any device that is used for measurement, that is supplied sterile, and that is in the body for less than 60 min requires two steps for CE marking. First, the inspection of the quality system that ensures accuracy of measurement and sterile supply must be carried out and certified by a Notified Body. A Notified Body is an organization accredited to confirm that a device meets the requirements of the EU Medical Device Directive (MDD). Second, the manufacturer must produce a Declaration of Conformity, indicating that their product meets the requirements of the MDD.

In the case of accreditation under FDA rule 510(k), the device must be proven "substantially equivalent" to an existing approved device. In the case of T-Doc AFCs there is in our view no precedent for this on the market, and it is unknown what equivalence and to which existing device was considered in the approval. Certainly no data comparing measurement characteristics were in the public domain at the time of approval.

A new drug or a new medical device requires extensive scientific evidence to show its clinical effectiveness and in some healthcare systems its cost effectiveness. The current promotion of the T-Doc AFC and the advice that it should replace the WFC is based on minimal scientific evidence in comparison to that required for therapeutic treatments, such as a new drug in an existing class of drugs. This may, by some, be regarded as acceptable, in the sense that the investigation of UDS is highly unlikely to harm the patient. This statement is only superficially correct. While UDS are very safe they are used for diagnosis prior to invasive therapies. The invasive therapies have a completely different scale of safety/risk compared with urodynamic investigation. Hence, if the urodynamic investigation is yielding incorrect measurement, leading to misdiagnosis and inappropriate use of invasive therapies, then the urodynamic technique can be responsible for causing patients harm, albeit indirectly. Hence the authors believe that any new method of investigation should be vigorously assessed. This statement is supported by the International Continence Society in its document of 2014[12] which states that all new urodynamic methods should be properly assessed.

On the Laborie website (www.laborie.com accessed 09.05.2016), the T-Doc air charged disposable catheters are described as

> *"faster and simpler to set up than any other technology. T-Doc air charged catheters are also less sensitive to patient movement. All this means less time per procedure, less time in set up and clean up and less staff training, which means more patients may be seen in less time. In addition, by eliminating the need to irrigate the patient with large quantities of water, disposable T-Doc catheters also improve hygiene and patient comfort."*

Furthermore, the website claims that a T-Doc AFC "records accurate abdominal pressures" and results in "more precise diagnosis". These statements are made without any scientific references and no literature can be found to substantiate these claims. These must, therefore, be regarded as marketing claims and of no scientific value. The authors contacted Laborie asking for any unpublished data concerned with the bench testing or clinical testing of the T-Doc system that would allow such claims to be made. Laborie reported[26] that they are currently reviewing the clinical data following their acquisition of T-Doc. They also reported that they are organizing further AFC versus WFC studies in Europe. The catalogs available and on-line data were searched and no reference was found as to the temperature stability, manufacturing tolerances, or expected accuracy of the T-Doc AFCs during urodynamic testing. Laborie were requested to supply such data, but to date only manufacturing quality control data have been received. This is at variance with the UK National Physical Laboratory requirement for data to be supplied in order to recognize the level of confidence in a measurement.

4 | BENCH TEST RECOMMENDATIONS

Since clinical studies have reported variability in UDS measurements made with T-Doc AFCs, it is recommended that bench testing be performed to assess the catheter-to-catheter variability of the AFCs. Awada et al. repeated each of their pressure chamber recordings in three different AFCs and found that they yielded highly repeatable results ($R = 0.9999$).[10] Although they only tested a very low number of catheters, this suggests that the variability in urodynamic recordings may be clinically related rather than due to equipment variability or unreliability, as discussed by Kranse and van Mastrigt.[15]

T-Doc AFCs and WFCs have been tested simultaneously in a pressure chamber under conditions simulating cough and Valsalva leak point pressure.[10] Further testing should include similar testing under conditions that simulate other urodynamic events such as voiding, non-voiding detrusor contractions (detrusor overactivity), and detrusor underactivity. In addition, the difference in outcomes between such bench-top testing studies and in vivo studies need to be explored to determine the causes of these differences. This sort of experiment is not easy to design but could, for example, include simulation of hypothesized causes for these differences in a pressure chamber. Imaging could be utilized during in vivo studies to view the location of catheter tips to see if they interact with bladder mucosa or other potential confounders. Also, the algorithm from Awada et al.[10] could be expanded to include the full pressure tracing, not just maximum pressures, and could potentially take into account differences in vivo as well.

5 | CLINICAL RECOMMENDATIONS

1. The use of AFCs in conventional (non-ambulatory) UDS is not recommended by the authors for neurological patients, male patients, and children, as there are no publications on the use of AFCs in these patient groups, and in particular there has been no comparison of the pressure readings of AFCs to reference pressure readings from WFC.
2. In female conventional (non-ambulatory) UDS, it is not recommended that AFCs are used when precise pressure measurements are required for diagnostic purposes. Should investigators feel that pressure patterns alone may give useful information, further validation testing will be required before routine use is acceptable. The two comparative clinical trials published for cystometry in non-neurological women,[16,18] show that there are differences in the pressures recorded by T-Doc AFCs compared to WFCs, but it is uncertain which system most reliably represents true pressure.
3. It is recommended that there is further validation of AFC measurement techniques, such as AFC test–retest reliability, such as have been done for WFCs, e.g., Ref.[27] Also, further work on specific quality control methods, for instance, feasible resting pressure ranges, is essential as these have not been described for AFCs.
4. It is recommended that further research is carried out in order to identify what causes the differences in pressure readings obtained by AFCs and WFCs identified by the published studies.
5. It is recommended that researchers should work with the manufacturers of AFCs and WFCs to define their physical characteristics and to evaluate future clinical data, in order to develop good urodynamic practice guidelines for AFCs. The ICS could have a governing role in this regard.

6 | CONCLUSIONS

This review found two papers on bench testing and two clinical papers in the peer reviewed literature that compared the performance of T-Doc AFCs with WFCs during cystometry. There are no other peer-reviewed data in the public domain. These data make it clear that there are statistically significant differences in the pressures recorded by the two, but the causes of these differences are unknown. Despite little evidence for clinical validity, T-Doc AFCs are being widely marketed and used. The evidence base supporting the use of AFCs, including

air charged catheters, differs markedly from that required by regulatory authorities, such as the FDA, for new treatment methods such as for drugs and medical devices used in lower urinary tract disorders (LUTD). New investigational methods are important and should be subjected to a similar level of scrutiny as, although they may not do direct harm to patients, they may cause harm indirectly through the misdiagnosis of LUTD, resulting in invasive treatment either being inappropriately used or withheld.

At present, AFCs should not be used as a direct replacement of WFCs, in conventional (non-ambulatory) UDS, except within good quality research studies designed to evaluate their clinical effectiveness as a diagnostic methodology. In the absence of proper regulatory oversight, professional multi-disciplinary organizations such as the ICS should take responsibility to advise the clinical community as to when there is sufficient good quality evidence to justify the use of AFCs, and in what clinical circumstances.

POTENTIAL CONFLICTS OF INTEREST

Dr Abrams reports personal fees and other from Astellas, Ferring, Pfizer, and Ipsen, during the conduct of the study; Mr Gammie reports grants from Laborie, Mediwatch, Andromeda, Digitimer, and Gaeltec, outside the submitted work; Dr Toozs-Hobson reports grants from NIHR, personal fees from Allergan, Syner Med, non-financial support from Astellas, personal fees, and non-financial support from SEP, outside the submitted work; Mr Niblett reports other from Exeter Scientific Developments Ltd, during the conduct of the study; personal fees from Malvern Medical Group, outside the submitted work. In addition, Mr Niblett has royalties paid from sales of the Exeter catheter system; Dr Hosker and Mr Kightley has nothing to disclose; Dr Rosier reports grants from Astellas, grants from Laborie/MMS/Tdoc, grants from ONO-Pharma, outside the submitted work. Dr. Damaser reports other from TDOC, LLC, other from Laborie, Inc., outside the submitted work; in addition, Dr. Damaser has a patent Standardized Measurement of Physiological Pressures Using an Air-Charged Catheter Apparatus licensed.

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