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Classification of Male Lower Urinary Tract Symptoms Using Mathematical Modelling and a Regression Tree Algorithm of Noninvasive Near-Infrared Spectroscopy Parameters

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Abstract

Background: Assessment of bladder outlet obstruction (BOO) is standard clinical practice in patients with lower urinary tract symptoms (LUTS). This is currently achieved through pressure–flow studies. Research indicates that progressive functional impairment of the bladder due to BOO is associated with haemodynamic changes. Near-infrared spectroscopy (NIRS) is an optical method of monitoring tissue oxygenation and haemodynamics via changes in concentration of the chromophores oxyhaemoglobin (O₂Hb) and deoxyhaemoglobin (HHb).

Objective: To report a noninvasive technique and mathematic method of analysis for assessment of BOO in male subjects using NIRS and to test the independent ability of NIRS data to distinguish between patients with and without obstruction using a classification and regression tree algorithm (CART).

Design, setting, and participants: A prospective cohort study to evaluate subjects presenting for urodynamic assessment of LUTS using standard urodynamic studies with simultaneous transcutaneous NIRS monitoring. The NIRS data (magnitude and pattern of changes in O₂Hb and HHb) were analysed, and a CART algorithm was constructed. Sixty-four males referred for evaluation of LUTS were studied at a tertiary care, university-based research and clinical facility.

Measurements: Clinical symptoms were classified using the International Prostate Symptom Score (IPSS). Pressure–flow studies were done with simultaneous transcutaneous NIRS monitoring of the detrusor. Pressure–flow studies were classified according to the Abrams-Griffiths nomogram. NIRS data documented changes in the concentration of the chromophores O₂Hb and HHb.

Results and limitations: IPSS scores ranged from 12 to 34, with a mean of 19. The pressure–flow nomogram found 30 patients with BOO, 16 patients without BOO, and 18 patients with equivocal results. The CART found a misclassification error of 4% with 88% specificity and 94% precision. The NIRS instrument and algorithm were new; no asymptomatic subjects were studied.

Conclusion: Using a CART algorithm, noninvasive NIRS data during voiding had independent discriminatory ability related to classification of BOO.

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1. Introduction

Bladder outlet obstruction (BOO) is commonly associated with lower urinary tract symptoms (LUTS) in men [1]. BOO is a mechanical phenomenon; therefore, it is normally studied using mechanical parameters, such as pressure and flow. Intuitively, if obstruction in a fluid-transporting system is present, pressure must be increased to transmit the usual flow [2]. This is physiologically justified because the detrusor satisfies the Hill model of muscle contraction [2,3], which expresses the inverse relationship between detrusor strength and flow at a given bladder volume. This translates into the bladder-output relation (BOR) [4], the approximately inverse relationship between detrusor pressure (P_{det}) and flow. Due to the BOR, obstruction is associated with high P_{det} and/or low flow.

Urodynamic tests are the current standard for classification of the degree of obstruction [1]. Pressure–flow studies constitute the gold standard for diagnosing BOO, through the use of the Abrams–Griffiths [5] and Schäfer [6] nomograms. With the Abrams–Griffiths nomogram, obstruction is diagnosed by plotting the values of maximum flow (Q_{max}) and P_{det} at Q_{max} ($P_{\text{det}}[Q_{\text{max}}]$). This point can fall in one of the three regions of the nomogram: obstructed, unobstructed, and equivocal for obstruction.

Recently, a noninvasive [7–11] and invasive [12] optical method for monitoring the bladder detrusor using near-infrared spectroscopy (NIRS) has been described. NIRS is an established, basic science technique that was first applied to in situ human tissue in 1977 [13–16] and was used in urological research in 1990 [17]. The technology has evolved to enable several tissues and organs to be studied and a range of parameters to be measured [14]. NIRS uses near-infrared (NIR) light introduced into tissue transcutaneously to monitor changes in tissue oxygenation and haemodynamics [13,16]. This is achieved by measurement of changes in the concentration of naturally occurring compounds called *chromophores* that absorb NIR light, depending on their concentration and chemical structure [18]. The principal chromophores of interest in urologic applications of NIRS are oxyhaemoglobin ($O_2\text{Hb}$) and deoxyhaemoglobin (HHb) [8,9,11]. Two physics principles underlie NIRS: (1) light in the NIR spectrum, unlike visible light, penetrates skin and scatters in tissue, and (2) oxygen-dependent changes in chromophore concentration can be measured because the absorption spectra of $O_2\text{Hb}$ and HHb are different at specific wavelengths in the NIR region [13,18]. Chromophore concentration (expressed in $\mu\text{mol}/100\text{ ml}$) is measured in real time as a change relative to baseline. Changes in total haemoglobin concentration (tHb), derived from the sum of the $O_2\text{Hb}$ and HHb, indicate a change in blood volume [9,10,13,16].

Applications in a variety of urologic conditions have principally evaluated vascular and haemodynamic aetiologies [8,9,17]. The bladder detrusor can be monitored via a noninvasive suprapubic sensor during simultaneous urodynamic studies of filling and emptying [7,8,9]. Following preliminary animal and human trials [8], our hypothesis was that NIRS-derived patterns of change in $O_2\text{Hb}$ and HHb

concentrations observed during voiding would differ between patients presenting with LUTS who were classified as obstructed or unobstructed using pressure–flow studies [11]. This study was performed to evaluate the ability of mathematical modelling and analysis of NIRS data via a classification and regression tree (CART) algorithm [19] independently to classify subjects assessed as obstructed or unobstructed using invasive urodynamic data and nomogram classification.

2. Methods

This study received ethical approval (HO6-70108) from the University of British Columbia ethics board.

2.1. Participants

Participants included ambulatory male patients referred to the University of British Columbia Bladder Care Centre with LUTS for urodynamic evaluation. LUTS were defined according to the International Continence Society. Participants had not undergone surgical treatment of the lower urinary tract and were not on medical treatment for their symptoms. The medical histories obtained reflected normal practice for urodynamic evaluation of patients with LUTS.

2.2. Procedure

Following informed consent, subjects completed an International Prostate Symptom Score (IPSS) questionnaire, and their height and weight were recorded. The IPSSs were tabulated along with body mass index (BMI). A dipstick urinalysis was performed to determine the presence of nitrates. Patients suspected of having a urinary tract infection or who had gross haematuria on a voided specimen were not tested.

Urodynamic studies were then conducted with simultaneous NIRS monitoring throughout the filling and voiding cycle. The NIRS instrument was designed for urologic studies (URO-NIRS, Urodynamic Technologies Ltd., Vancouver, BC, Canada) with three lasers (wavelengths: 785 nm, 808 nm, and 830 nm) transmitting light via a multi-filament optical glass fibre bundle to an emitter in a self-adhesive sensor patch that also incorporates a photodiode receiver. The separation between the emitter and the receiver was 4 cm.

In each subject, a NIRS sensor patch was applied on the abdominal skin 2 cm above the pubis across the midline; NIRS baseline data were collected for 30 s; permission was given to void into a flow meter (Laborie Medical Technologies Inc., Mississauga, ON, Canada). On completion, residual urine volume was determined using a catheter; a filling cystometrogram (CMG) and pressure–flow study were completed [6] using French double lumen urethral catheter, rectal balloon, and electromyography (EMG). For the filling cycle, water at room temperature was infused at 50 cm^3 per minute. Simultaneous synchronised data collection occurred at 6 Hz (changes in concentration of $O_2\text{Hb}$, and HHb, urodynamic pressure, and uroflow). The data stream was marked to record permission to void, time of uroflow start, Q_{max} , and time of uroflow cessation. The interval defined as the voiding interval was the time from the start of uroflow to the end of uroflow.

2.3. Data analysis

Patients' pressure–flow curves were classified as obstructed, unobstructed, or equivocal using the Abrams–Griffiths nomogram [5]. Then a preliminary classification procedure using NIRS changes in chromophore concentration ($O_2\text{Hb}$, HHb, and tHb [$O_2\text{Hb} + \text{HHb}$]) was performed using

linear discriminant analysis (LDA) [20]. Specifically, LDA was applied to discriminate between obstructed and unobstructed regions using $P_{det}(Q_{max})$ and relative concentrations of chromophores at Q_{max} . Next, a CART-model algorithm [19] was constructed using MATLAB software (The Mathworks, Inc., Natick, MA, USA) to assess the patterns of change in chromophore concentration throughout the whole voiding cycle. To do this, the changes in concentration of O_2Hb and HHb from baseline were taken from the raw NIRS data for every time point at 6 Hz from the start of uroflow to the end of uroflow. Data from patients categorised as equivocal by the Abrams-Griffiths nomogram were excluded, but all data points (throughout voiding) for all subjects classified as obstructed and unobstructed were incorporated into the learning sample for the CART. A decision tree, which is a recursive partition of the learning sample [19], was then generated from this data. Cross-validation and calculation of the misclassification rate for future observations followed. This computational technique divided the sample into subgroups and used each group as a sample to test the error.

3. Results

Seventy patients were enrolled, and 64 NIRS data sets were analysed. Four were incomplete because of technical difficulties relating to the NIRS data: fibre-optic cable failure ($n = 3$) and a data saving error ($n = 1$). Two were excluded by haematuria ($n = 2$), a potential confounder due to NIR light absorption. Mean age was 62 yr (range: 49–91 yr). IPSS scores ranged from 12 to 34 (mean: 19). BMI ranged from 18 to 35 (mean: 25). There were no subjects with diabetes.

By Abrams-Griffiths classification of the urodynamic data, 30 of the 64 subjects (47%) were obstructed; 16 of the subjects (25%) were unobstructed; and 18 of the subjects (28%) were equivocal for obstruction. Subjects in the obstructed zone had a Q_{max} ranging from 2 cm^3/s to 18 cm^3/s (mean: 11 cm^3/s), and a $P_{det}(Q_{max})$ ranging from 7 cm to 150 cm of water (mean: 73 cm). For subjects in the unobstructed zone, Q_{max} ranged from 2 cm^3/s to 38 cm^3/s (mean: 15 cm^3/s) and the $P_{det}(Q_{max})$ ranged from 5 cm to 87 cm of water (mean: 27 cm). Subjects that were equivocal for obstruction had a Q_{max} ranging from 2 cm^3/s to 19 cm^3/s (mean: 10 cm^3/s) and a $P_{det}(Q_{max})$ ranging from 0 cm to 44 cm of water (mean: 34 cm).

Data from the 46 subjects classified as obstructed or unobstructed were used for subsequent analysis. Scatter plots of the three relative chromophore concentrations (O_2Hb , HHb , and $tHb [O_2Hb + HHb]$) relative to $P_{det}(Q_{max})$ are shown in Figs. 1–3.

LDA of each of these NIRS data sets gave the same misclassification error of 16%, while application of the CART algorithm resulted in a misclassification error of 4%. The CART calculation used a learning sample in which a learning set consisted of the relative concentrations of O_2Hb and HHb for patients classified according to the Abrams-Griffiths nomograms classifications of obstructed or unobstructed. Elements in the learning set were paired [$HHb(t)$, $O_2Hb(t)$] for every time t in the time series of recorded data. The total number of pairs in the learning set was 37 540.

The following classification responses were obtained: true-positive fraction (TP) = 30, true-negative fraction (TN) = 14, false-positive fraction (FP) = 2, false-negative

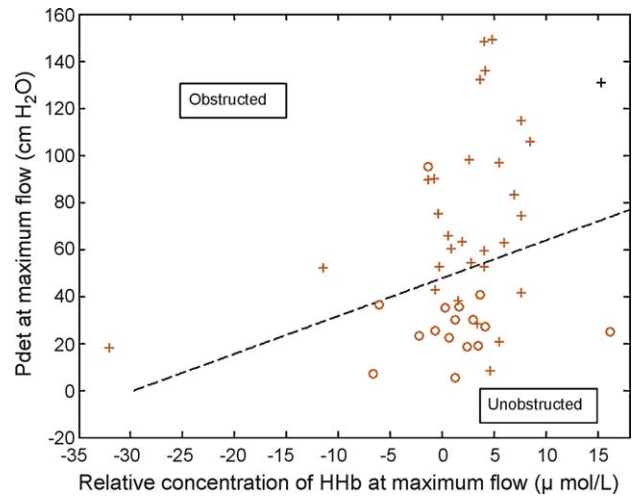


Fig. 1 – Detrusor pressure (P_{det}) at maximum flow (Q_{max}) versus relative concentration of deoxyhaemoglobin (HHb) at Q_{max} . Patients classified as obstructed according to the Abrams-Griffiths nomogram are plotted using crosses (+), whereas patients classified as unobstructed are plotted using circles (o). The dashed line represents the best line dividing the data set in two regions, obstructed and unobstructed, according to the linear discriminant analysis.

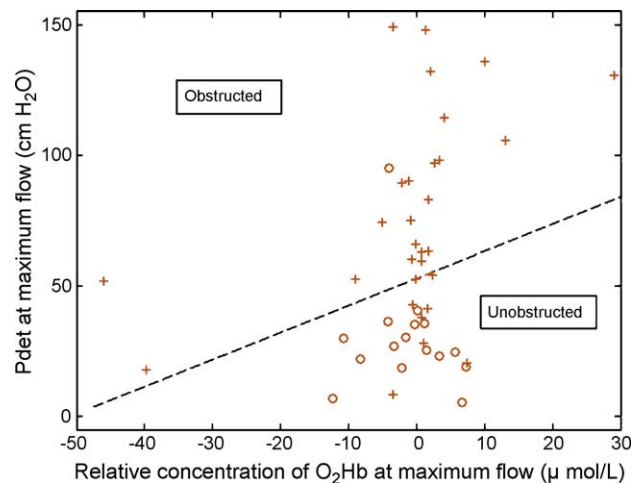


Fig. 2 – Detrusor pressure (P_{det}) at maximum flow (Q_{max}) versus relative concentration of oxyhaemoglobin (O_2Hb) at Q_{max} . Patients classified as obstructed according to the Abrams-Griffiths nomogram are plotted using crosses (+), whereas patients classified as unobstructed are plotted using circles (o). The dashed line represents the best line dividing the data set in two regions, obstructed and unobstructed, according to the linear discriminant analysis.

fraction (FN) = 0. From these fractions, the specificity and sensitivity of the method were calculated: sensitivity = $TP / (TP + FN) = 1$; specificity = $TN / (TN + FP) = 0.8750$; and precision = $TP / (TP + FP) = 0.9375$.

4. Discussion

This study reports simultaneous, noninvasive NIRS monitoring of changes in detrusor concentration of O_2Hb and HHb and conventional invasive pressure–flow measurements in men with LUTS. The scatter plots derived indicate that this group of patients could be divided into obstructed

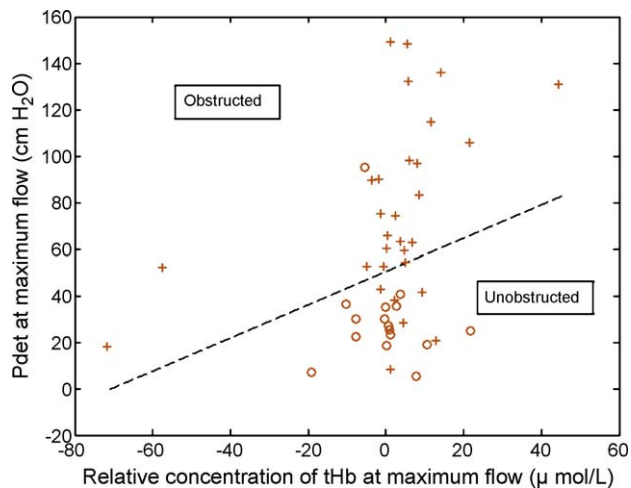


Fig. 3 – Detrusor pressure (P_{det}) at maximum flow (Q_{max}) versus relative concentration of total haemoglobin (tHb) at Q_{max} . Patients classified as obstructed according to the Abrams-Griffiths nomogram are plotted using crosses (+), whereas patients classified as unobstructed are plotted using circles (o). The dashed line represents the best line dividing the data set in two regions, obstructed and unobstructed, according to the linear discriminant analysis.

and unobstructed groups based on $P_{det}(Q_{max})$ and relative change in concentration of O_2Hb and HHb . LDA adds information on the relevance of different variables. Because the LDA misclassification error for O_2Hb and HHb is the same, only one of these equivalent relative concentrations and $P_{det}(Q_{max})$ are required for a linear classification of the presence of obstruction. However, classification is also possible using the noninvasive NIRS data alone, where analysis using a CART algorithm identifies those with and without obstruction with excellent sensitivity and specificity.

Because NIRS measures optical parameters influenced by physiologic changes occurring in the detrusor microcirculation and urodynamic measurements reflect pressure, NIRS chromophore concentration changes and urodynamic pressures can be expected to have a relationship based on current knowledge of the pathophysiology of obstruction, which includes elements of vascular change in the aetiology and evolution of BOO. Animal-model data suggest that a reduction in detrusor blood flow occurs in BOO [21,22]). Belenky et al [23] showed that BOO is associated with a reduction in blood flow to the detrusor using pressure–flow and Doppler studies, and Levin [24] described detrusor hypertrophy and accompanying alterations in innervation and metabolic factors as effects of outlet obstruction in humans. We have previously reported significant synchrony between P_{det} and NIRS chromophore changes in females with LUTS [8].

However, NIRS changes in chromophore concentration reflect the dynamic and sometimes multidirectional relationship that exists between tissue oxygen saturation, venous oxygen saturation, oxygen delivery, and other parameters dictating tissue respiration [16,25]. Hence, NIRS data from monitoring changes in detrusor oxygenation

and haemodynamics are nonlinear in nature. Therefore, where NIRS data are analysed alone, nonparametric data analysis will be more discriminating. Hence, our application of a CART algorithm in this study and the degree of specificity and sensitivity achieved in classifying subjects with BOO is based on NIRS data alone.

CART is a nonparametric classification algorithm based on decision trees [19]. CART use includes applications to other spectroscopic data and clinical situations in which there is no prior knowledge of the probability distribution of the data [19,26–28]. Examples where CART have been used successfully include the segregation of patients with unknown primary carcinoma into groups with similar clinical features and survival [27], and accurate separation of patients with and without myocardial infarction on admission to the emergency department [28]. Because of this capability, we used CART methodology, recognising that NIRS of the bladder detrusor is a new application of this technology, and that the majority of NIRS parameters measured do not have an established gold standard of measurements for comparison [13,14,16].

Currently, pressure–flow studies and their related nomograms provide the gold standard for the classification of patients as obstructed or unobstructed, and they use a single point to establish this classification [2]. The relationship of this point to NIRS data in our study is shown by linear models. However, a proportion of patients fall into an equivocal zone on the Abrams-Griffiths nomogram and are not definitively classified according to this methodology. For this reason this group was excluded from our data analysis. While the CART algorithm could be used to classify the equivocal group, doing so would generate data that could not be verified against any gold standard. In future studies where the CART analysis of NIRS data is used, performing a series of measurements in patient's classified as equivocal by urodynamic testing would allow the clinician to ultimately validate classification of these subjects as unobstructed or obstructed as their LUTS evolve.

In contrast to the single point used for urodynamic classification, the NIRS algorithm uses data from changes occurring in the detrusor throughout the whole voiding cycle. Hence, patterns of change, trends, and magnitudes of change in oxygenation and blood volume are included. This may explain the excellent ability of CART analysis of the NIRS data to discriminate even though the spread of chromophore change appears similar between groups. It is possible that further research with NIRS will enable patients to be classified by other factors, apart from pressure, which are probably involved in the pathophysiology of BOO. For example, factors relating to oxygenation and haemodynamics may be relevant. Prior research using Doppler flow probe studies in humans does indicate that blood flow tends to increase with increasing volume and pressure [29]. Consequently, as NIRS chromophore concentration changes reflect variations in detrusor oxygenation and blood volume [7–11], NIRS data collected simultaneously with pressure flow data should provide further insight into vascular and haemodynamic mechanisms related to BOO. Another

example would be the potential of NIRS to quantify degrees of obstruction and/or the contribution of specific underlying diseases that are known to influence the vascular system, including diabetes and arteriosclerosis. Future studies would benefit from additional clinical history and screening for markers of vascular disease. Such screening could include, for example, lipid profiles, haemoglobin A1C, blood pressure, and echocardiogram.

Confidence that NIRS monitors change within the detrusor and that chromophore concentration changes observed are a valid reflection of physiologic effect come from observations that include ultrasound confirmation of bladder position related to NIRS sensor placement; knowledge of the depth of penetration of NIR light into tissue; the fact that significant chromophore change only occurs in relation to temporal events during voiding; the fact that simultaneous recording at an abdominal site remote from the bladder yields no evidence of change; and observations from animal and human studies that specific physiologic events (eg, hypoxia, ischaemia, and changes in blood volume) generate similar patterns of change in the detrusor as seen in other tissue (eg, brain and muscle) [8,10,13,16].

The sensitivity and specificity of the CART nomogram developed in this study suggest that further studies are warranted. The NIRS technique is attractive to patients because it is noninvasive and because the laser-generated light used is not toxic. A prospective study would enable further precision of the CART algorithm to be established and would allow the ability of NIRS to classify equivocal patients to be investigated. Simultaneous NIRS and urodynamic testing would allow the pathophysiology related to the vascular effects of obstruction to be more comprehensively described and would allow pretreatment and posttreatment values to be evaluated. We suggest that, because NIRS monitoring with this algorithm has this degree of discrimination ability and is also noninvasive, it is a promising alternative to current invasive pressure–flow studies that should be evaluated in conjunction with current diagnostic methods. In this way, it will be possible to evaluate the contributions that NIRS can make to more comprehensive diagnosis in BOO and also to establish whether it has a place used alone as a noninvasive screening option.

4.1. Limitations

This is a study using a new NIRS instrument and software. However, the instrument incorporates conventional laser wavelengths in the NIR spectrum that are used for other basic science and clinical NIRS studies. Also, the software algorithms generate patterns of change comparable to those seen in response to standard physiologic challenge (ischaemia and hypoxia) by investigators using a range of NIRS instruments to study a variety of tissues [8,13,14,16]. This study is limited to male subjects with LUTS described by the IPSS scoring system; it did not include observations in asymptomatic subjects; it excluded patients classified as equivocal from urodynamics data; and it did not measure

observations after treatment which would be relevant to further studies. Other confounders such as the presence of urinary tract infection and haematuria could potentially affect the NIRS observations. The presence of a urinary tract infection was tested using a urinalysis of nitrates and white blood cells, presenting clinically with dysuria. Patients with gross haematuria were not part of this study. The presence of gross haematuria could result in erroneous observations of haemoglobin within the field, and for this reason such patients were not included. In this study clinical history reflected current practice for patients referred for urodynamics. There were no diabetics in this cohort. However, clinical history and related screening for established vascular disease was not done.

5. Conclusions

Simultaneous measurements of invasive pressure–flow and noninvasive, NIRS-derived changes in O₂Hb and HHb concentrations in the detrusor were conducted in male patients with LUTS. When P_{det}(Q_{max}) values and NIRS changes were analysed using LDA, a relatively good classification of subjects with and without obstruction resulted. However, because the patterns of change in O₂Hb and HHb are nonlinear, the use of a CART algorithm is more applicable. Using CART, the noninvasive NIRS data have an independent ability to distinguish between patients with and without obstruction, with good sensitivity and specificity.

Author contributions: Lynn Stothers had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Stothers, Macnab.

Acquisition of data: Stothers, Macnab.

Analysis and interpretation of data: Guevara, Stothers, Macnab.

Drafting of the manuscript: Guevara, Stothers, Macnab.

Critical revision of the manuscript for important intellectual content: Stothers, Macnab

Statistical analysis: Guevara.

Obtaining funding: None.

Administrative, technical, or material support: Stothers, Macnab.

Supervision: Stothers, Macnab.

Other (specify): None.

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Editorial Comment on: Classification of Male Lower Urinary Tract Symptoms Using Mathematical Modelling and a Regression Tree Algorithm of Noninvasive Near-Infrared Spectroscopy Parameters

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Near-infrared spectroscopy (NIRS) can detect changes in oxygenation and haemodynamics, such as those caused by hypoxia, ischaemia, or changes in blood volume. NIRS has been used to assess brain oxygenation [1] and has also been used in a number of chronic health conditions (eg,

chronic heart failure, vascular disease, chronic obstructive pulmonary disease, muscle diseases, renal failure). Up to this point, NIRS has seemed promising but not precise enough to allow monitoring by this technique alone in any of the mentioned conditions [2].

The authors are congratulated on presenting the first study to evaluate the possible clinical usefulness of NIRS in voiding disorders [3]. Their results demonstrate that changes in oxygenation are significantly different in the voiding phase of patients with and without bladder outlet obstruction (BOO). Doppler ultrasound studies have previously demonstrated that voiding can lead to changes in vesical blood flow [4]. Therefore, measurement of changes in oxygenation and haemodynamics provides

additional information and adds to the understanding of voiding dysfunction caused by vascular/haemodynamic pathology.

NIRS does not measure BOO but rather changes in oxygenation that correlate with BOO. Thus, other relevant influences on oxygenation changes need to be assessed in future studies. Because chronic BOO can lead to detrusor hypertrophy, it would be important to measure bladder wall thickness. Furthermore, the influence of vascular diseases (eg, diabetes mellitus, arteriosclerosis) on bladder haemodynamics should be evaluated. Chronic BOO may lead to changes in oxygenation which might not be present in patients with an acute onset or with a lesser extent of BOO [5]. Until there is no evidence that measurement of oxygenation correlates with BOO and not with secondary changes, the same is true for NIRS in BOO as for its use in other diseases: NIRS is promising but not yet ready to be used as a reliable substitute for standard techniques.

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