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Development of Urodynamic Standards for Quality Control

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1. Introduction

1.1 Anatomy of the lower urinary tract

Initially, a brief summary of the anatomy of the lower urinary tract will be presented.

The bladder is a hollow muscular organ in pelvis lined by a mucous membrane and covered on its outer aspect partly by peritoneal serosa and partly by fascia (Lich et al. 1978; Dixon and Gosling 1987). The muscularis of the bladder is formed of smooth muscle cells which comprise the detrusor muscle. The detrusor muscle is often described as consisting of three layers, the muscle fibres of the outer and inner layers tending to be orientated longitudinally, while those of the middle layer are circularly disposed. Woodburne (1960) has clearly shown that the musculature of the bladder is a "muscular meshwork". The constituent muscle bundles frequently branch and reunite with one another to form this interlacing meshwork. The bladder is profusely supplied with autonomic nerve fibres which form a dense plexus among the smooth muscle cells (Dixon and Gosling 1987).

In the male bladder neck, the smooth muscle cells form a complete circular collar which forms the internal urethral sphincter and extends distally to surround the preprostatic portion of the urethra. In the female bladder neck, muscle bundles extend obliquely or longitudinally into the urethral wall. There is the rich sympathetic innervation in the male bladder neck, while the female bladder neck is well supplied with the parasympathetic innervation (Gosling et al. 1977; Dixon and Gosling 1994).

The male urethra is considered in four regional parts: preprostatic, prostatic, membranous and spongiose. In the membranous urethra, muscle coat consists of a relatively thin layer of smooth muscle bundles and a layer of circularly orientated striated muscle fibres forming the external urethral sphincter. In the female urethra, the muscle coat consists of an outer sleeve of striated muscle, which forms the external sphincter together with an inner coat of smooth muscle fibres (Dixon and Gosling 1994).

1.2 Physiology of the lower urinary tract

Briefly the physiologic functions of the lower urinary tract will be described.

The lower urinary tract functions as a group of interrelated structures whose joint function is to bring about efficient bladder filling and urine storage and its voluntary expulsion. During bladder filling at physiologic rates, intravesical pressure initially rises slowly despite large increase in volume. Physical distensibility or higher compliance, slowly physiologic filling rate and inhibition of detrusor contraction are the major characters of physiologic function of the bladder during filling phase. There is a gradual increase in proximal urethral resistance, and urethral pressure is always greater than intravesical pressure during the bladder filling. Many factors have been thought to contribute to proximal and distal urethral closure mechanism (Arsdalen and Wein 1991; Torrens 1987).

Normal voiding is a voluntary act which results in sustained contraction of the detrusor muscle and relaxation of the urethra until the bladder is empty. Voiding can be divided into the initiation of voiding, the continuation of voiding and the termination of micturition. At the initiation of voiding, urethral closure pressure progressively drops, and this pressure drop occurs slightly before a corresponding increase in detrusor pressure with urinary flow when the detrusor pressure exceeded the urethral pressure. Then, the bladder pressure begins to increase. Descent of the bladder base is initiated by relaxation of the pelvic floor muscles and continued by relaxation of the urethra, and the bladder neck opens. This process is accompanied by the bladder outlet assuming a funneled shape (Tanagho and Miller 1970; Torrens 1987). At some specific intravesical pressure, the sensation of bladder distention is perceived, and micturition is initiated voluntarily at an appropriate time, proceeding to completion and involving a decrease in bladder outlet resistance and contraction of the bladder smooth musculature. Whilst the initiation of voiding is a voluntary act, its continuation depends on a more automatic activity. Micturition can be initiated by voiding reflexes almost regardless of the capacity of the bladder.

Normally, the bladder is very accurate in its ability to void exactly the capacity within itself with a voiding pressure which is maintained at a very constant level. Occasionally, the bladder seems to over- or under-estimate the capacity it has to deal with. Under-estimation results in the bladder continuing to contract after it is empty, resulting in an isometric increase in contraction pressure known as "after contraction"; this seems to have no identified pathologic significance (Torrens 1987).

The physiologic functions of lower urinary tract can be summarized as two aspects (Arsdalen and Wein 1991).

Bladder filling and urine storage

- increasing volumes of urine at a low intravesical pressure and with appropriate sensation must be accommodated.
- the bladder outlet must be closed at rest and remain so during increases in intraabdominal pressure.
- no involuntary bladder contraction can occur.

Bladder emptying

- a coordinated contraction of the bladder smooth musculature of adequate magnitude must occur.
- a concomitant lowering of resistance must occur at the level of the smooth sphincter and the striated sphincter.
- no anatomic obstruction can occur.

1.3 Urodynamics

Urodynamics is the medical science concerned with the physiology and pathophysiology of urine transport from the kidneys to the bladder as well as its storage and evacuation (Susset

1985). There are two basic aims of urodynamics: to reproduce the patient's symptomatic complaints and to provide a pathophysiological explanation for the patient's problems (Abrams 1997).

1.3.1 The history of urodynamics

Urodynamics can trace its roots to the 1800s, when instrumentation was first developed and described for the measurement of bladder pressure and urine flow rate; however, the term *urodynamics* was only recently coined by Davis (Davis 1954; Perez and Webster 1992).

1.3.1.1 The history of cystometry

Even prior to the invention of the cystometer, intravesical pressure had been measured by several European investigators, with Dubois in 1876 perhaps being the first (Smith 1968). In 1882, Mosso and Pellacani had shown that bladder pressure rose due to the contraction of the detrusor muscle (Perez and Webster 1992). In 1897, Rehfisch described an apparatus used for the simultaneous measurement of vesical pressure and urinary volume (Derezic 1988). In 1927, Rose coined the term cystometer and described its development and clinical usefulness (Rose 1927; Perez and Webster 1992); and he found cystometry to be a much more accurate way to determine the neurologically abnormal bladder than cystourethroscopy. Up to 1933, Denny-Brown and Robertson used a specially designed double catheter and a photographic recording method to measure pressure in the bladder, urethra and rectum (Denny-Brown and Robertson 1933). They showed in humans that bladder pressure is independent of intraabdominal pressure, and they were also the first to note and name the after contraction. In 1948, Talbot used the terms stable and unstable bladder detrusor in his study on spinal cord injury patients (Talbot 1948). In the modern era, technologic advances undoubtedly wrote the history of cystometry, in particular emerging of computerized urodynamic system. The application of the computer technology and electronic pressure transducers (external transducer and microtransducer) made the measurement and analysis in cystometry much more accurate.

1.3.1.2 The history of uroflowmetry

Before the invention of the uroflowmeter, Rehfisch in 1897 recorded the timing of onset and finish of micturition (Derezic 1988). In 1922, Schwartz and Brenner measured indirectly urethral exit pressure, then calculated the velocity of exiting urinary stream (Smith 1968). In 1925, Gronwall made the first recordings of unimpeded urinary flow (Smith 1968). None of these investigators made accurate calculation of flow rate. In 1948, Drake reported the development of the *uroflowmeter*; he developed an instrument that measured the increasing weight of urine against a factor of time on a kymograph and called the graphs produced uroflowgrams (Drake 1948; Perez and Webster 1992). In 1956, von Garrelts reported the use of electronics to record voiding rates; he used a transducer to convert changes in pressure of urine collected onto a photokymograph (von Garrelts 1956).

1.3.1.3 The history of pressure-flow study

With von Garrelts' classic article and Davis' book entitled *Mechanisms of Urologic Diseases*, the 1950s represented the infancy of modern urodynamics. Davis' book inspired much interest in the simultaneous measurements of uroflowmetry and cystometry (Perez and Webster 1992). In 1956, von Garrelts reported the normal micturition pressures electronically in men; in 1963, Zinner and Paquin did that in women (Zinner and Paquin 1963). In 1960, Murphy and Schoenberg reintroduced the measurement of micturition pressures by using

suprapubic cystometry (Murphy and Schoenberg 1960). In 1962, Gleason and Lattimer reported the use of cystometry and uroflowmetry in combination to determinate bladder outlet strictures indirectly that was called as the *pressure-flow study* (Gleason and Lattimer 1962), and drew back the prologue of modern urodynamic studies on bladder outflow obstruction (BOO). In 1971, Griffiths introduced the concept of *fluid mechanics of collapsible tubes*, in relation to the conduit function of the lower urinary tract (Griffiths 1971). In the early 1980s, Schäfer introduced the concept of *passive urethral resistance relation, PURR* (Schäfer 1981; 1983), making the understanding to physiology of micturition much more profound. These were mathematically and biophysically elegant, computerized statements of the then-current understanding of bladder, bladder neck and urethral physiology and pathophysiology. They hearkened back to the call the 1968 meeting on *"The Hydrodynamics of Micturition"* for models that were based on the best urology and bioengineering (Boyarsky 1998). Up to now, these concepts have still being used in clinical and basic research widely, and have a role of guiding. The achievement of basic research must be applied to clinical practice, and must serve it. In 1979, Abrams and Griffiths reported a pressure-flow rate plot for classifying bladder outflow as obstructed, equivocal and unobstructed conditions (Abrams, Griffiths 1979). This Abrams-Griffiths (A/ G) nomogram has been used for classification of obstruction in clinical practice. Afterwards, Schäfer developed and reported a nomogram for grading BOO using PURR principle (Schäfer et al. 1989; 1990). He further simplified PURR and introduced the *Linear PURR (L-PURR)* concept so that the clinical use of his nomogram became easier (Schäfer 1990). Schäfer nomogram divided bladder outflow obstruction into 7 grades from 0 to VI. As a semi-quantitative method for assessment of BOO, it has been known well by clinician, and has been applied to clinical practice widely. Basing on these nomograms mainly, the International Continence Society (ICS) recommended a nomogram as a standard for assessment of BOO (Griffiths et al. 1997).

1.3.1.4 The history of urethral pressure measurements

In 1923, Bonney reported crude measurements of bladder and urethral pressures; then, Kennedy described an innovative method to measure urethral resistance in 1937 (Perez and Webster 1992). In 1953, Karlson reported the simultaneous measurements of pressure in the bladder and internal and external urinary sphincters (karlson 1953). In 1969, Brown and Wickham reported a simple method, *the urethral pressure profile (UPP)*, to measure the pressure exerted by the urethral wall at every point of its length (Brown and Wickham 1969). For some years, UPP as a tool for the evaluation of patients with incontinence and BOO; however, in the current, it enjoys only limited application in its simple form (Perez and Webster 1992).

1.3.1.5 The history of Videourodynamics

In 1930, Thomsen reported the first series of lateral voiding cystourethrograms in female patients; and Muellner and Fleischner used the fluoroscope to study normal and abnormal micturition extensively (Muellner and Fleischner 1949; Perez and Webster 1992). In 1967, Miller described that truly popularized the use of cinefluoroscopy in conjunction with the other lower urinary tract urodynamic studies (Miller 1967). This was the birth of what has become known as videourodynamics, which includes the simultaneous recording and projection of fluoroscopic and functional data (Perez and Webster 1992). In 1970, Bates et al. reported the simultaneous cinefluoroscopy and pressure-flow studies, and discovered the combination of studies necessary for the evaluation of a variety of micturition dysfunction (Bates et al. 1970).

1.3.2 Urodynamic laboratory techniques

1.3.2.1 Uroflowmetry

Uroflowmetry is the simplest and least invasive test. With the developments in urine flowmeters, the clinical use of uroflowmetry has become widespread. The common flowmeter involves urine falling onto a disc rotating at a constant speed. The mass of the urine tends to slow the rotation, but a servomotor keeps the speed constant. The power necessary to do this is proportional to the urine flow rate. The urine volume can be derived by integration of the flow rate (Torrens 1987). Urine flow may be described in terms of rate and pattern and may be continuous or intermittent. Flow rate is defined as the volume of fluid expelled via the urethra per unit time. It is expressed in ml/ s. The maximum flow rate (Q_{max}) is the only value so far submitted to an extensive quantitative investigation. Voided volume, patient environment and position, way of filling (by diuresis or by catheter) as well as type of fluid can influence the results of uroflowmetry (Abrams et al. 1988). von Garrelts reported that there was a correlation between the Q_{max} and the square root of the volume voided (von Garrelts 1957). It is now quite clear that uroflowmetry give evidence of urinary dysfunction, and is a good screening test. However, urine flow rate is a combined produce of detrusor contractility and outlet resistance. Then, uroflowmetry cannot offer a precise diagnosis as to the cause of abnormal flow; for example it has poor diagnostic specificity for BOO, and cannot be used alone except in clearly defined situations (Abrams et al. 1997).

1.3.2.2 Cystometry

Cystometry is used to study both the storage and the voiding phases of micturition in order to make a diagnosis which enables effective treatment to be given (Abrams 1997).

1.3.2.2.1 Cystometry during filling

Cystometry during filling is the method by which the pressure/ volume relationship of the bladder is measured. All systems are zeroed at atmospheric pressure. For external transducers the reference point is the level of the superior edge of the symphsis pubis. For catheter mounted transducers the reference point is the transducer itself. Cystometry is used to assess detrusor activity, sensation, capacity and compliance. Present techniques allow the continuous recording of pressure within the bladder during artificial or natural filling. Before starting to fill the bladder the residual urine may be measured. Intravesical pressure is the pressure measured within the bladder. Abdominal pressure is the pressure surrounding the bladder and is usually measured as rectal pressure. Detrusor pressure (P_{det}) is calculated by electronically subtracting the abdominal pressure (P_{abd}) from the intravesical pressure (P_{ves}). The simultaneous measurement of abdominal pressure is essential for the interpretation of the intravesical pressure trace. During cystometry, any variations should be specified. Access for pressure measurement is most commonly by transurethral catheterization; occasionally a percutaneous suprapubic catheter is used. In current practice, the fluid medium is usually liquid (saline). The temperature of fluid is usually the same with that of room. The positions of patient may be in supine, sitting or standing; the different positions of can result in the different abdominal pressures, but detrusor pressure is constant. Certain cystometric parameters may be significantly altered by the speed of bladder filling. For the general discussion, the following terms for the range of filling rate may be used: up to 10 ml/ min is slow filling; 10 to 100 ml/ min is medium filling; over 100 ml/ min is rapid filling (Abrams et al. 1988). Bladder sensation is difficult to evaluate; it

usually assessed by questioning the patient in relation to the fullness of the bladder during cystometry. In patients with normal sensation, maximum cystometric capacity is the volume at which the patient feels he or she can no longer delay micturition. Compliance indicates the change in volume for a change in pressure. Compliance is calculated by dividing the volume change (ΔV) by the change in detrusor pressure (ΔP_{det}) during that change in bladder volume ($C=\Delta V/ \Delta P_{det}$). Compliance is expressed as mls per cm water.

1.3.2.2.2 Cystometry during voiding

Pressure-flow study of micturition is a method that the abdominal, intravesical, and detrusor pressures and flow rate are simultaneously recorded during the voiding phase of cystometry. With regard to the methodology, ICS has published an updated report on pressure-flow standardisation (Griffiths et al. 1997). The currently available urodynamic equipment is adequate for the accurate recording of pressures and flow. During investigation, the patients must be in the position as the usual voiding; and catheters should be as thin as possible, for example 6F double lumen. As standard transurethral double lumen catheter has been suggested to use; only in children and patients with severe constrictive obstruction a suprapubic pressure recording may have advantages. A rectal balloon catheter is recommended to use for abdominal pressure recording (Schäfer 1998). Many investigators have focused on the analysis of pressure-flow study. Because the ideas about the mechanical behavior of the urethra and the bladder were new, it was not immediately evident how to apply them in practice and so a number of competing approaches to the analysis of pressure-flow studies were developed (Abrams and Griffiths 1979; Schäfer W 1983; 1990; Griffiths et al. 1989; Spangber et al. 1989; Höfner et al. 1995). All of them share a similar fundamental basis, but there are differences in detail and in objectives. The results of pressure-flow studies may be used for various purposes, for example, for objective diagnosis of BOO or for statistical testing of differences in urethral resistance between groups of patients. For these purposes, methods have been developed to quantify pressure-flow plots in terms of one or more numerical parameters. The parameters are based on aspects such as the position, slope, and curvature of PURR of the plot. A/ G nomogram was based on data from 117 patients. The upper boundary line, separating clearly obstructed patients from others, was arrived at by a combination of theoretical insight and clinical judgment. A lower boundary separates clearly unobstructed patients from others. The equivocal region between these two boundaries contained a mixture of obstructed and unobstructed patients (Abrams and Griffiths 1979). Working independently, Schäfer developed the L-PURR method of grading BOO and modified to a nomogram: Schäfer nomogram (Schäfer 1990). Based on studies of the urodynamic changes following TURP, it provided 7 grades ranging from not obstructed to severely obstructed, 4 grades for the strength of the contraction ranging from very weak to strong. Grade II fulfills a similar function to the equivocal zone of A/ G nomogram: the upper between obstructed and equivocal or slightly obstructed are identical in A/ G nomogram and Schäfer nomogram. The position of the lower boundary of grade II suggests that the equivocal zone in A/ G nomogram is too large at the lower flow levels. Combining these aspects, ICS recommended a provisional nomogram; it is important for comparing results from different centers. Therefore, it is recommended that the upper boundary line of ICS nomogram should be used to distinguish between clearly obstructed patients and others; Schäfer nomogram may be used to grade the severity of obstruction; detrusor pressure at Q_{max} or AG number may be used to represent urethral resistance (Abrams et al. 1997).

1.3.2.3 Urethral pressure measurement

The urethral pressure and the urethral closure pressure are idealized concepts which represent the ability of the urethra to prevent leakage. The urethral pressure may be measured by a number of different techniques which do not always yield consistent values. Not only do the values differ with the method of measurement but there is often lack of consistency for a single method. For example, the effect of catheter rotation when urethral pressure is measured (Abrams et al. 1988). On the other hand, there still are some problems resulting in that distinction of physiological facts and urodynamic artifacts are difficult. One of the problems is caused by bring a probe into a closed system; another one is related to the dynamics (Schäfer 1998). These problems limited its application and interpretation for urethral closure function. Intraluminal urethral pressure may be measured: at rest, with the bladder at any given volume; during coughing or straining; during voiding. Measurement may be made at one point in the urethra over a period of time, or at several points along the urethra consecutively forming a urethral pressure profile (UPP).

1.3.2.4 Videourodynamics

Videourodynamics is the simultaneous radiological visualization and urodynamic measurement of lower urinary tract. Some centers use it as a first line investigation, this is unnecessary, hazardous and expensive. Videourodynamics is indicated when structural information is required as well as functional information. In neuropathic patients there is an increased prevalence of bladder shape abnormalities, vesicoureteric reflux, and urethral sphincter abnormalities; therefore, videourodynamics is the investigation of choice in suspected neuropathic vesicourethral dysfunction. It also is indicated in failed surgery for stress incontinence and in men who develop incontinence after prostatic surgery. It allows the clinician to differentiate between incontinence, secondary to sphincter damage and that due to detrusor instability (Abrams 1998). Videourodynamics, by combing the simultaneous measurement of detrusor pressure, flow rate and radiological visualization provides the most comprehensive urodynamic evaluation; however, there is no evidence that video adds clinical benefit, beyond that given by pressure-flow studies, in elderly men with suspected BOO (Abrams et al. 1997).

1.3.3 Quality control of urodynamic data

Undergoing the development, urodynamics has been applied to clinical practice widely, and has more and more important role at present. The aim of clinical urodynamics is to reproduce patient's symptoms under the condition of precise measurement in order to identify the underlying causes for the symptoms and to provide a pathophysiological explanation for them (Schäfer 1998). In clinical urodynamic practice, one of the most important problems is whether or not a reliable diagnosis can be made. A reliable diagnosis relies on a good urodynamic practice, which has a precise measurement with data quality control and accurate analysis of results. However, considerable data quality problems were found when traces from a study of multi-centers were examined. In analysis on the data from the ICS "benign prostatic hyperplasia (BPH)" study, Schäfer et al found that up to 60% of traces had significant technical errors and obvious artifacts. One of these could be easily corrected, and were due to common problems, such as, a difference in pressure transmission to the P_{ves} and P_{abd} tracings, incorrect position of the zero reference line, and spikes and other irregularities in the P_{ves} tracing. One third of artifacts were less easy to correct, such as periodic loss of a signal, pressure rising above full scale deflection, slow drift in a pressure tracing, and loss of the urethral catheter during voiding. A small percentage (10%) of traces

could not be analyzed due to a lack of scaling or indicated zero position, or complete loss of a pressure or flow signal (Schäfer et al. 1994). Although ICS published a series of reports on standardisation of urodynamics, some investigators did not perform urodynamic tests according to them; therefore, considerable technical errors and artifacts were produced. These indicate that data quality control has not received enough attention or has lacked consensus, and the urodynamic practice is badly in need of the standards for quality control. Data quality control has substantial contents, it mainly involves the following aspects: equipment set-up and configuration before measurement; signal testing, plausibility check, pattern recognition and artifacts correction during investigation; and retrospective analysis and artifacts correction for results after study. Quality control and plausibility check during investigation are the best way to avoid and to correct artifacts at an early stage. Quality control relies on pattern recognition and knowledge of typical values (Schäfer 1998).

Quality control during urodynamic investigation can avoid and eliminate various artifacts and technical errors. However, it is difficult to acquire a perfect measurement in clinical urodynamic practice. Therefore, there are either more or less artifacts and errors existed in urodynamic data. For these artifacts existed in data, retrospective quality control and correction are necessary. Especially, computer's application to clinical urodynamic practice makes the retrospective quality control more important. The computer-based urodynamic systems have gradually replaced traditional ones, have been playing a role in many aspects of urodynamics. However, computer's application has also brought some problems into urodynamics. Up to now, a true urodynamic expert system has not yet been developed. Many computer printouts are inferior to traditional paper-chart records. Computer is not able to pick up technical artifacts and human errors. Some investigators accept the automated result of computer without question (Lewis et al. 1997). The studies of manual correction in uroflowmetry have been performed by some investigators. Rowan et al found that up to 20% uroflow traces showed artifacts (Rowan et al. 1987). Grino et al compared manual and automated values, and found consistently lower values of Q_{max} in manual readings (Grino et al. 1993). Madsen et al compared manual and computerized values of Q_{max} and detrusor pressure at Q_{max} ($P_{det.Qmax}$) in a small group of patients, and found some different pressure-flow results between manual and computerized groups (Madsen et al. 1995). From these views, quality control in retrospective data analysis is necessary.

1.3.4 Standard for quality control of urodynamic data

The study on quality control of urodynamic data is lacking in the published literature. In order to carry out quality control, the urodynamic standards for it are crucial. Schäfer et al drafted the ICS standards of "*Good Urodynamic Practice*" which have been presented and discussed at two ICS meetings in 1997 and 1998, and was published in 2002 (Schaefer et al. 2002). This report has provided us with the standards and guideline for quality control of urodynamic data. Certainly, the project of this dissertation has been carried out along this line.

1.4 Objectives

The aim for this dissertation is to develop the urodynamic standards for quality control. This aim will be achieved by two strategies in two stages:

- Quality control during investigation: there are two strategies:
  - To establish the typical value ranges (TVR) as the tool for quantitative plausibility check and quality control;

  - To describe the typical signal patterns (TSP) as the tool for qualitative plausibility check and quality control.
- Quality control in retrospective analysis:
  - To recognize and correct the technical errors and artifacts in computerized urodynamic data using the above-mentioned strategies;
  - To evaluate the impact of the technical errors and artifacts on the outcome by comparing the computerized results with manual one, and to indicate the significance of retrospective quality control.

2. Materials and methods

A total of 181 elderly males with lower urinary tract symptoms (LUTS) was recruited in the study. The mean age of the males was 65.3 years, with a range of 43 ~ 86 years.
All cystometric measurements were done in standing or sitting position with 30 ml/ min infusion rate using Dantec Menuet urodynamic system. During cystometry, the patient was asked to cough before and at beginning of filling, at regular intervals during filling phase, and before and after voiding. For each patient, a free uroflowmetry was recorded before cystometry. Methods, definitions and units comforted to the standards proposed by the ICS except where specifically noted (Abrams et al. 1988).
The study was retrospective. A total of 606 cystometric traces from the males was reviewed. The traces that were non-interpretable and non-correctional because of various artifacts and technical errors were excluded in the study; then, a total of 582 cystometric traces was included for further analysis. All traces were manually read, and various technical errors and artifacts were recognized and corrected.

2.1 Establishing the typical value ranges

For each trace, P_{ves} and P_{abd} estimated from rectal pressure were recorded simultaneously; and P_{det} was calculated by the electronic subtraction of P_{abd} from P_{ves}. The overactive detrusor factors were ruled out when the filling end point was defined. Maximum cystometric capacity (MCC), Q_{max}, $P_{det.Qmax}$ and volume voided (V_{void}) were recorded and read. Compliance of bladder was calculated by dividing the volume change by the change in detrusor pressure during that change in bladder volume. The values of P_{ves}, P_{abd} and P_{det} were read before, at beginning and at end of filling, and at end of voiding respectively. For each moment above-mentioned during cystometry, the mean value, standard deviation, median, 95% confidence interval (CI), and 50%, 80% and 95% TVR as well as upper limit of 99% range were calculated using computer in each parameter. The technical errors and atypical changes that were relevant to TVR were classified and given some examples to indicate the role and significance of quantitative plausibility check using TVR in cystometry.

2.2 Describing the typical signal patterns

For describing TSP, the signals' scales recorded were 40 cm H_2O per cm for P_{ves}, P_{abd} and P_{det}, and 4 ml/ s per cm for uroflow rate; the scales of time axis were 1 minute per cm during filling and 15 seconds per cm during voiding. The changes corresponding to cough tests were observed and compared among P_{ves}, P_{abd} and P_{det} tracings. In data analysis, we classified the signal patterns of pressures into four types: I. fine structure (noise); II. minimal dynamic changes caused by breathing, talking and moving (minor changes); III. major changes due to regular cough tests; IV: typical major changes related to straining, detrusor

overactivity, rectal contractions and detrusor contraction. The fine structure of pressure signal shows a "live" signal tracing with some minimal amplitude signal variations (noise). Straining is characterized by pressure increases on the P_{ves} and P_{abd} tracings but not on the P_{det} tracing; detrusor overactivity has the unstable waves recorded on P_{ves} and P_{det} tracings but not on P_{abd} tracing; rectal contraction shows a positive wave on the P_{abd} tracing and a negative artifact or dip on the P_{det} tracing but not on P_{ves} tracing. Typical pattern of detrusor contraction is that P_{ves} and P_{det} tracings increase and decrease with uroflow tracing smooth and steady. According to it, we can identify several special patterns of detrusor contraction: after-contraction, fluctuation contraction and unstable detrusor voiding. These four types of signal patterns were compared among P_{ves}, P_{abd} and P_{det} tracings at beginning of filling, during filling, before, during and after voiding respectively. Then, typical signal patterns of pressures were described; the relevant errors and artifacts were given some examples and analyzed to indicate the role and significance of qualitative plausibility check using TSP recognition in cystometry.

2.3 Quality control in retrospective analysis

In the study on retrospective quality control, all traces were printed out, and were manually read. The readers were blinded to the computer results. For each trace, artifacts during filling and voiding were examined according to typical value ranges and typical signal patterns. During filling cystometry, artifacts involved mainly the wrong initial resting pressures, spikes related to test-coughs and periodic signal loss or stepwise changes. During voiding cystometry, artifacts in uroflow and pressures were recognized and were corrected to indicate the effect of quality control. The recognition and correction of Q_{max} artifacts contain two aspects of value and location. Firstly, Q_{max} must be located at the highest plateau on a main uroflow curve. The additional modifications in flowrate and the spike artifacts on a main uroflow are smoothed and corrected to get Q_{max} value. Secondly, the spike artifact located at beginning or end of uroflow tracing, which is recognized as Q_{max} by computer, must be corrected. Reader has used the following two specifications to read manually Q_{max}: 1. Q_{max} must be measured at the highest plateau or peak of the flow curve that lasted for 2 seconds or more; 2. Q_{max} value must be read to the nearest 0.5 to 1.0 ml. per second. Various artifacts and errors during voiding cystometry may occur on P_{ves} and P_{abd} tracings, then influence P_{det} tracing. The pressure artifacts have been classified into technical and physiologic ones. The technical artifacts may be caused by phasic signal loss, signal stepwise changes and catheters' dislocations and others. The physiologic artifacts may be the spikes and dips on P_{det} tracing resulted from the different causes. We have described three common causes. The first one is the spikes due to the different transmissions between P_{ves} and P_{abd} tracings corresponding to straining. The second one is the dips caused by rectal contractions. The last one is the spikes or the dips due to urethral sphincter overactivity during voiding, which is sphincter contraction or relaxation. In the study, any rapid rising and dropping of P_{det} tracing were recognized as spike and dip artifacts, and were smoothed and corrected manually.

In analysis of pressure-flow data, various parameters and different methods were employed. As a continuous quantitative parameter, obstruction coefficient (OCO) developed by Schäfer et al was used to detect the difference in urethral resistance between manual and computerized results, and was calculated according to the following formula: $OCO = P_{det.Qmax}/ 40+2Q_{max}$ (Schäfer and Sterling 1995). Schäfer nomogram was used to grade the degree of obstruction and to evaluate the changes of obstructed grade after correction

(Schäfer 1990). International Continence Society (ICS) nomogram were used to classify and diagnose obstruction and to find the shifts of classifications due to correction (Griffiths et al. 1997).

The different statistical analyses were performed using computer. The correlation analyses between manual and computerized results were done in the following variables: Q_{max}, $P_{det.Qmax}$ and OCO. In above mentioned variables, the variations between manual and computerized values were evaluated by the matched-pairs z test for a big sample. The percentages in various grades of Schäfer nomogram and classification of ICS were calculated. The variations in classification of ICS nomogram and in grades of Schäfer nomogram between manual and computerized readings were examined by chi-square test and relative to an identified distribution (Ridit) analysis respectively. In above mentioned statistical analyses, $p<0.05$ was considered significant.

3. Results

The results were shown from three aspects: establishing TVR, describing TSP and retrospective quality control.

3.1 Establishing the typical value ranges

At the different moments during cystometry, TVR for various pressures and other parameters were shown in the following tables. Taking 50% as a usual range, we can find that before and at beginning of filling TVR for P_{ves} and P_{abd} were 31~42 cmH_2O and 28~39 cmH_2O in standing or sitting position respectively; and that of P_{det} was 0~4 cmH_2O with a mean of 2.3 cmH_2O, which was very close to zero (Table 1). These ranges were TVR for initial resting pressures. The upper limits of 95% and 99% ranges for P_{det} were 9 and 13 cmH_2O respectively (Table 1); then, we took 10 cmH_2O as the upper limit of a maximum possible resting value for P_{det}. With these TVR for initial resting pressures, we can check the technical errors and artifacts occurred in zero setting and a pressure reference level establishing retrospectively.

	Mean±SD	Median	95% CI	50%	80%	95%	99% upper limit
P_{ves} (cmH_2O)	35.4 ±10.7	37	0.87	31~42	24~46	7~51	63
P_{abd} cmH_2O)	33.1±10.9	35	0.88	28~39	20~44	5~49	59
P_{det} (cmH_2O)	2.3±3.5	2	0.29	0~4	0~6	0~9	13

Table 1. The mean value, standard deviation, median, 95% confidence interval (CI), and 50%, 80% and 95% typical value ranges as well as upper limit of 99% range for initial resting pressures in cystometry

According to a definite value: P_{det} cannot be negative and a relatively definite value: initial resting P_{det} is rarely over 10 cmH_2O, we can divide these errors relating to initial resting pressures into three types. Type I error has a normal initial resting P_{det}, but both P_{ves} and P_{abd} are wrong; type II has a negative initial resting P_{det}; and type III error has a too high initial resting P_{det} (over 10 cmH_2O). Concerning type I error, there are two sub-types: a. both initial resting P_{ves} and P_{abd} are too low comparing with their TVR (Fig. 1a); b. both P_{ves} and P_{abd} are too high comparing with their TVR (Fig. 1b).

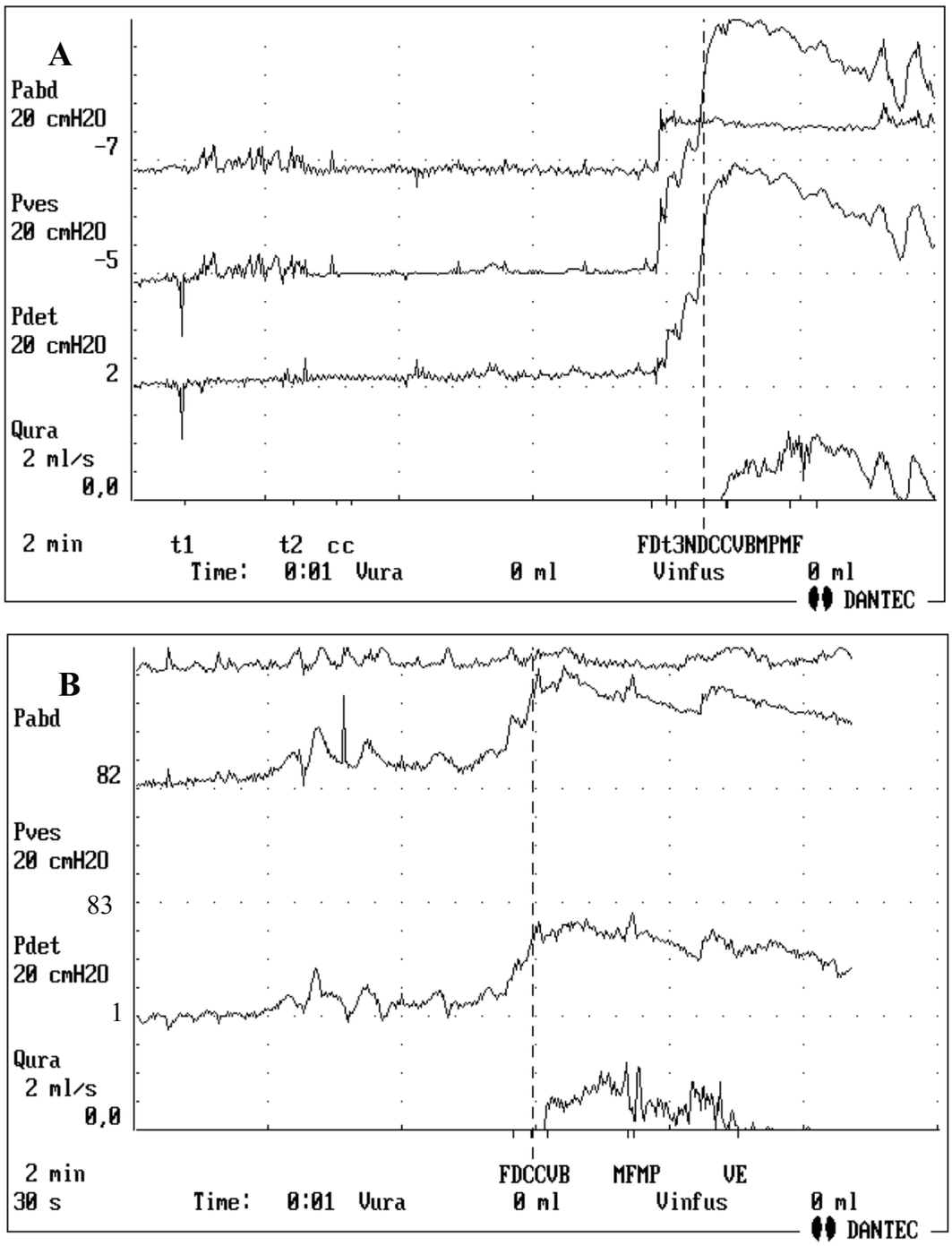
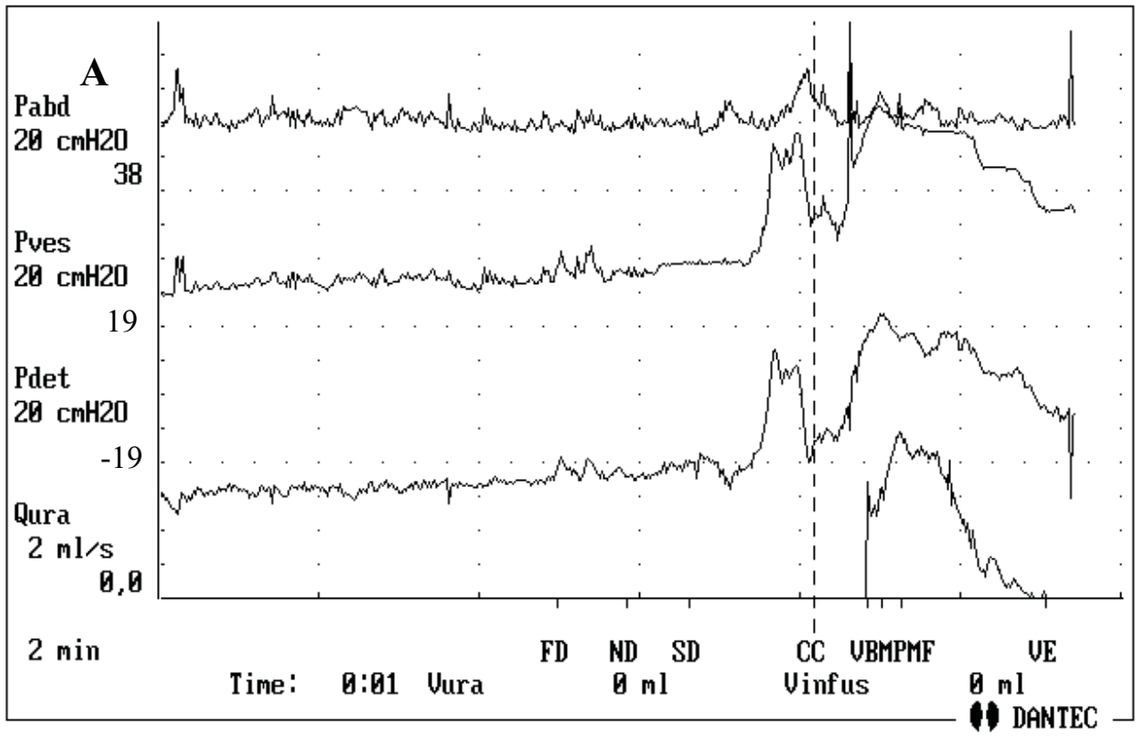


Fig. 1. Type I error related to typical value ranges for initial resting pressures. **A**: type Ia error has a normal initial resting P_{det}, but both P_{ves} and P_{abd} are too low comparing with their TVR; in this case, P_{det} is 2 cmH_2O, but P_{ves} and P_{abd} are -5 cmH_2O and -7 cmH_2O respectively. **B**: type Ib error has a normal initial resting P_{det}, but both P_{ves} and P_{abd} are too high comparing with their TVR; in this case, P_{det} is 1 cmH_2O, but P_{ves} and P_{abd} are 83 cmH_2O and 82 cmH_2O respectively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Pabd
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38
Pves
20 cmH2O
19
Pdet
20 cmH2O
-19
Qura
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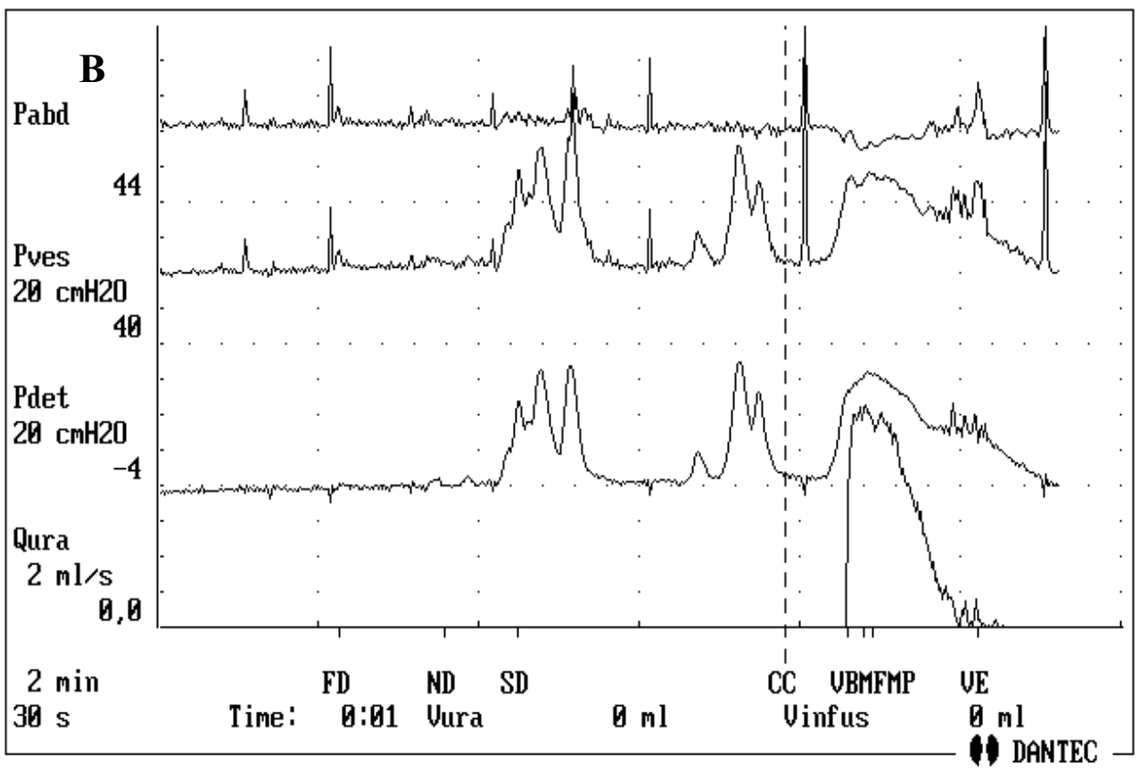
0,0
2 min
FD ND SD
CC VBMPMF
VE
Time: 0:01 Vura
0 ml
Vinfus
0 ml
DANTEC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Pabd
44
Pves
20 cmH2O
40
Pdet
20 cmH2O
-4
Qura
2 ml/s
0,0
2 min
30 s
FD ND SD
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VE
Time: 0:01 Vura
0 ml
Vinfus
0 ml
DANTEC

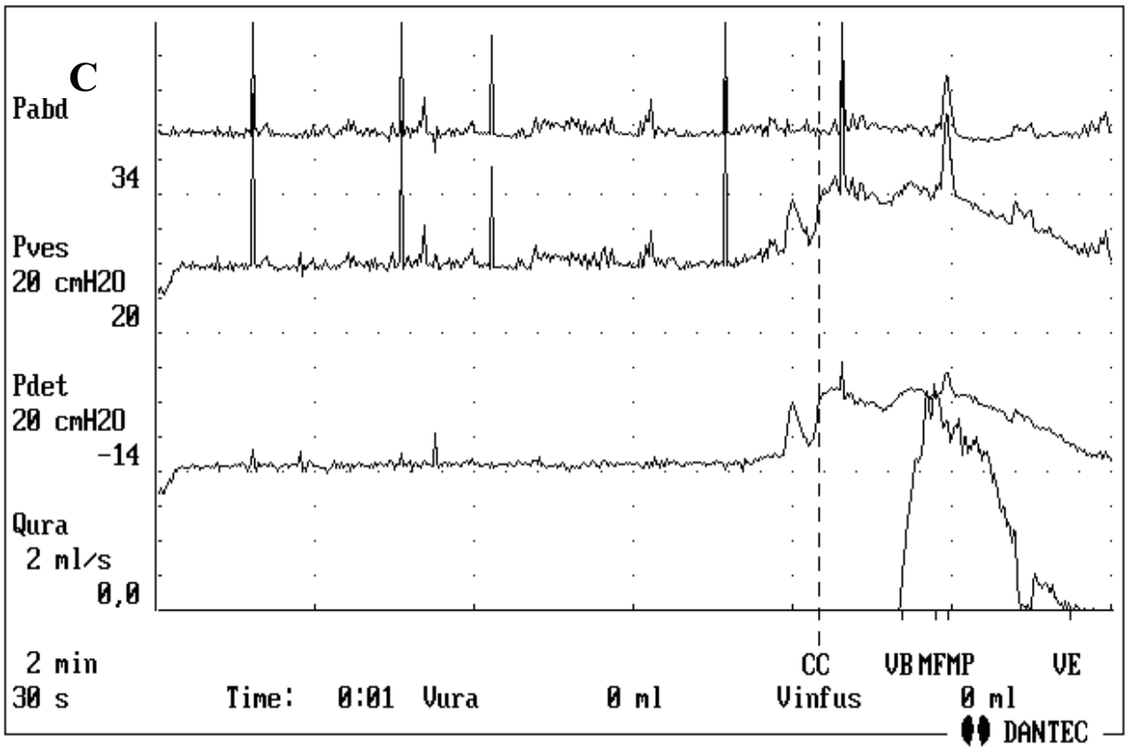


Fig. 2. Type II error related to typical value ranges for initial resting pressures. **A**: type IIa error has a negative initial resting P_{det} caused by a too low P_{ves} comparing with its TVR; in this case, P_{det} is -19 cmH_2O, P_{ves} and P_{abd} are 19 cmH_2O and 38 cmH_2O respectively. **B**: type IIb error has a negative initial resting P_{det} caused by a too high P_{abd} comparing with its TVR; in this case, P_{det} is -4 cmH_2O, P_{ves} and P_{abd} are 40 cmH_2O and 44 cmH_2O respectively. **C**: in this case, initial P_{det} is negative (type IIa error), then becomes positive during initial 30 seconds of filling. At beginning of filling, P_{det} is -14 cmH_2O, P_{ves} and P_{abd} are 20 cmH_2O and 34 cmH_2O respectively

There are two reasons leading to type II error: a. initial resting P_{ves} is too low comparing with TVR while initial resting P_{abd} is in TVR (Fig. 2a); b. initial resting P_{abd} is too high while P_{abd} is in TVR (Fig. 2b). In type II error, P_{det} value may become positive during initial 30 seconds of filling in some traces (Fig. 2c).

Also, there are two reasons resulting in type III: a. initial resting P_{ves} is too high comparing with TVR while initial resting P_{abd} is in TVR (Fig. 3a); b. initial resting P_{abd} is too low while P_{abd} is in TVR (Fig. 3b).

In the traces analyzed, the incidences of I, II and III errors were 9.8%, 4.5% and 1.4% respectively. P_{det} signal of 11.5% traces with type II error returned to TVR during initial 30 seconds of filling.

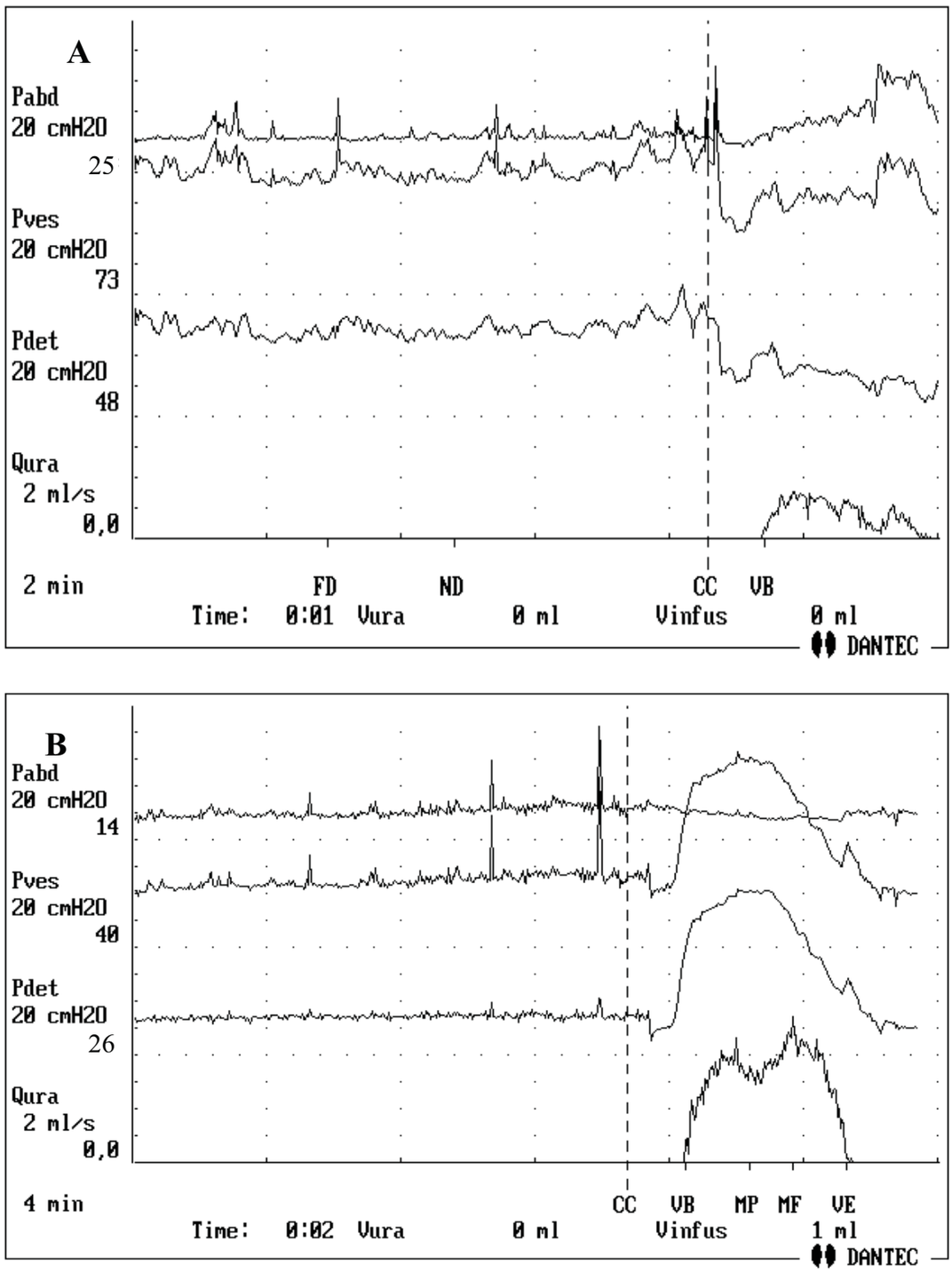


Fig. 3. Type III error related to typical value ranges for initial resting pressures. A: type IIIa error has a high initial resting P_{det} caused by a too high P_{ves} comparing with its TVR; in this case, P_{det} is 48 cmH_2O, P_{ves} and P_{abd} are 73 cmH_2O and cmH_2O respectively. B: type IIIb error has a high initial resting P_{det} caused by a too low P_{abd} comparing with its TVR; in this case, P_{det} is 26 cmH_2O, P_{ves} and P_{abd} are 40 cmH_2O and 14 cmH_2O respectively

At end of filling, TVR of P_{ves}, P_{abd} and P_{det} were 38~50 cmH_2O, 30~41 cmH_2O and 5~10 cmH_2O respectively. TVR of MCC and compliance were 157~345 ml and 26.7~70.8 ml per cmH_2O (Table 2). It means that P_{det} increases 5~6 cmH_2O during filling phase.

	Mean±SD	Median	95% CI	50%	80%	95%	99%
P_{ves} (cmH_2O)	42.4±12.5	43	1.02	38~50	29~56	10~62	80
P_{abd} (cmH_2O)	34.2±12.3	36	1.0	30~41	20~47	2~51	63
P_{det} (cmH_2O)	8.2±4.9	7	0.40	5~10	4~13	2~18	28
MCC (ml)	261.6±136.9	244	11.13	157~345	105~441	49~587	651
C (ml/ cmH_2O)	58.5±61.1	41.5	4.99	26.6~70.8	17.8~122.8	7~220	345

Table 2. The mean value, standard deviation, median, 95% confidence interval (CI), and 50%, 80% and 95% typical value ranges as well as upper limit of 99% range for pressures, maximum cystometric capacity (MCC) and compliance (C) at end of filling in cystometry

During voiding, TVR of P_{abd} at relaxation was 25~38 cmH_2O (Table 3). A typical relevant error, called type IV error, was that P_{abd} became negative at relaxation during voiding; and this error lead to a meaningless P_{det} value that was higher than P_{ves} (Fig. 4). In the traces analyzed, the incidence of this type of error was 0.7%. TVR of Q_{max}, $P_{det.Qmax}$ and V_{void} were 5.5~9 ml/ s, 57~92 cmH_2O and 167~315 ml respectively (Table 3). On the other hand, TVR of Q_{max} and V_{void} in free uroflowmetry were 8~9.2 ml/ s and 167~301 ml (Table 3). It means that Q_{max} and V_{void} during cystometry are comparable with those of free uroflowmetry.

	Mean±SD	Median	95% CI	50%	80%	95%	99%
Voiding cystrometry							
$P_{det.Qmax}$ (cmH_2O)	76.5±31.7	70	2.57	57~92	42~118	37~159	216
$P_{det.min.void}$ (cmH_2O)	44.6±18.9	40	1.62	30~53	23~70	20~92	107
$P_{abd.relax}$ (cmH_2O)	31.5±10.9	32	0.88	25~38	18~44	8~50	69
Q_{max} (ml/ s)	7.3±2.6	7	0.21	5.5~9	4~10.7	2.9~13	15
V_{void} (ml)	250.8±119.9	234	10.09	167~315	114~406	63~560	628
Free uroflowmetry							
Q_{max} (ml/ s)	7.9±2.8	8	0.36	8~9.2	4.2~11.4	3.1~15	16.8
V_{void} (ml)	242.4±109.9	233	13.99	167~301	120~374	87~493	689

Table 3. The mean value, standard deviation, median, 95% confidence interval (CI), and 50%, 80% and 95% typical value ranges as well as upper limit of 99% range for pressures, Q_{max} and voided volume (V_{void}) during voiding cystometry and free uroflowmetry

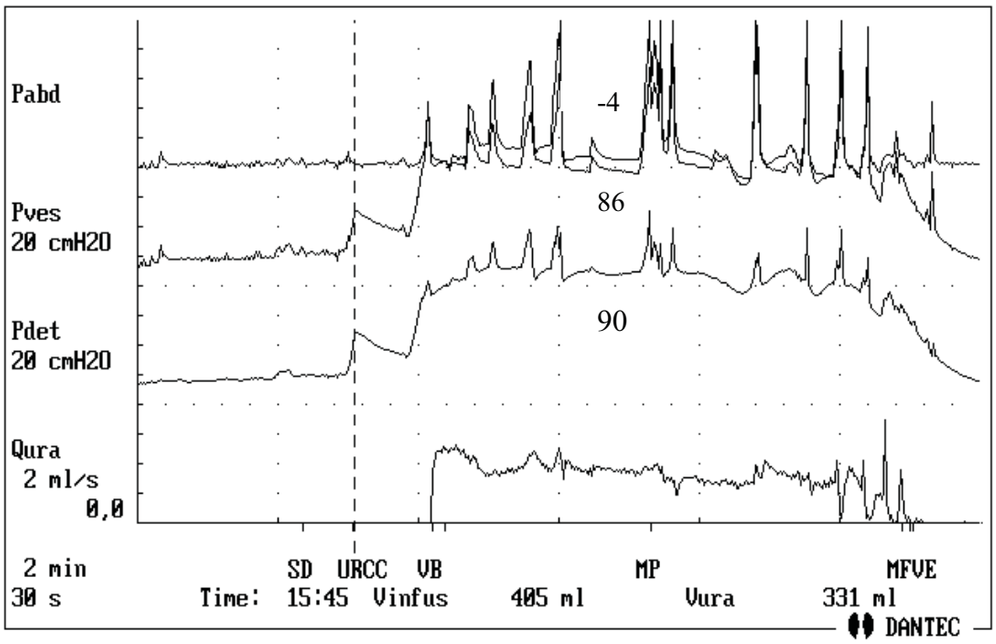


Fig. 4. Type IV error related to typical value ranges for P_{abd} during voiding. This type of error shows that P_{abd} becomes negative during voiding due to over relaxation of pelvic floor, and it leads to a meaningless P_{det} value that is higher than P_{ves}. The error usually has a low initial resting P_{abd}. In this case, during voiding P_{abd} around Q_{max} is -4 cmH_2O, P_{ves} and P_{det} are 86 cmH_2O and 90 cmH_2O respectively; and initial resting P_{abd} is 5 cmH_2O, initial P_{ves} and P_{det} are 9 cmH_2O and 4 cmH_2O respectively (type Ia error)

At end of voiding, TVR of P_{ves}, P_{abd} and P_{det} were 40~55 cmH_2O, 30~41 cmH_2O and 10~14 cmH_2O respectively (Table 4).

	Mean±SD	Median	95% CI	50%	80%	95%	99%
P_{ves} (cmH_2O)	48.5 ±13.4	47	1.09	40~55	35~64	26~79	108
P_{abd} (cmH_2O)	34.3±10.0	35	0.81	30~41	22~45	10~50	61
P_{det} (cmH_2O)	14.2±11.3	11	0.92	10~14	13~19	16~29	47

Table 4. The mean value, standard deviation, median, 95% confidence interval (CI), and 50%, 80% and 95% typical value ranges as well as upper limit of 99% range for post-void pressures in cystometry

Comparing these TVR with those before voiding, we found P_{abd} had little change, P_{ves} and P_{det} were close to the levels before voiding. Also, there were two types of relevant errors. One (type V error) was that P_{ves} and P_{det} after voiding still kept high levels beyond their TVR while a high post-void residual volume was ruled out. There may be two reasons leading to this error: a. post-void P_{ves} is too high but P_{abd} normal, and P_{ves} tracing becomes a high level "dead" line during voiding due to the signal loss or urethral catheter dislocation (Fig. 5a); b. post-void P_{abd} is too low due to the rectal catheter dislocation or the signal loss of P_{abd} tracing during voiding (Fig. 5b).

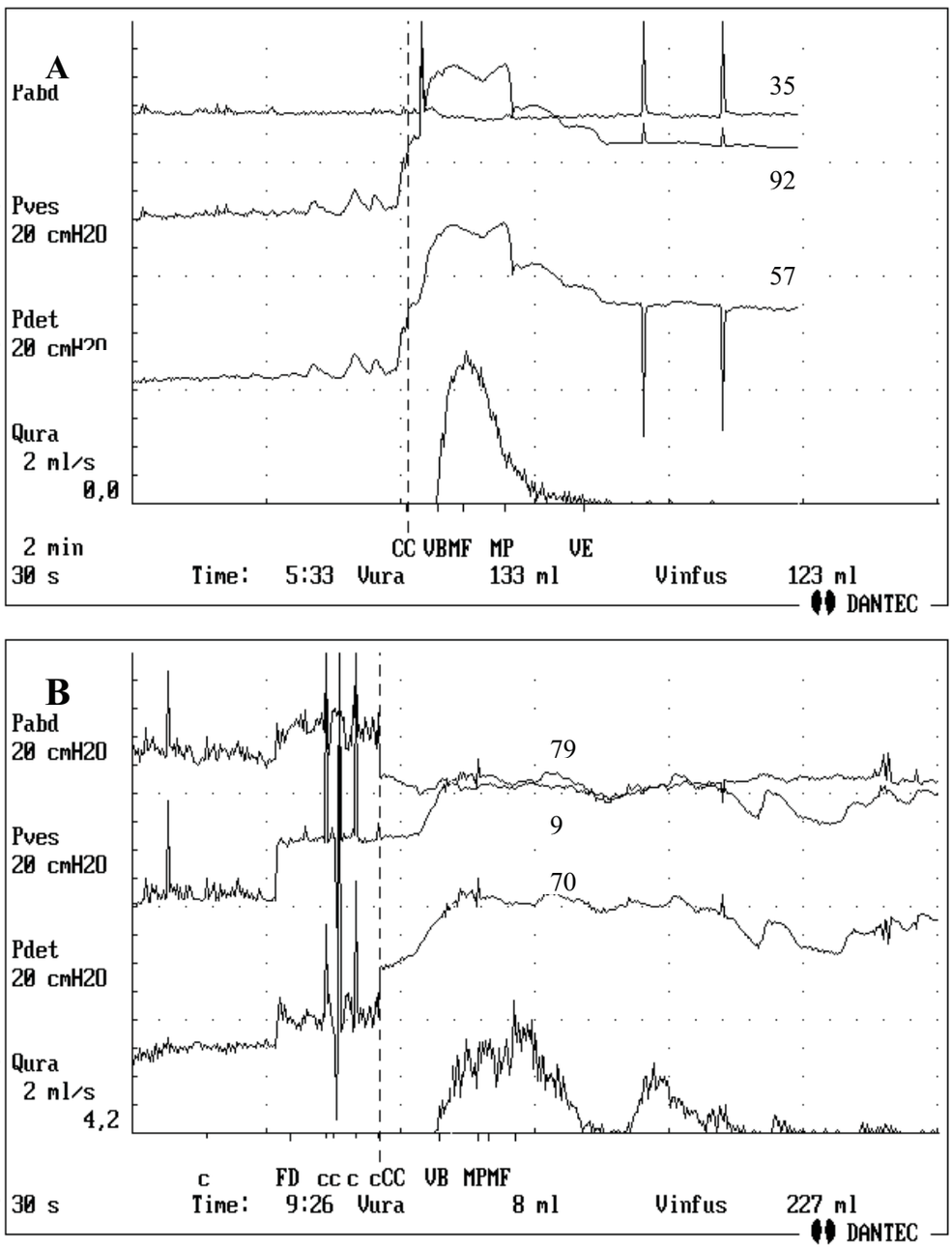


Fig. 5. Type V error related to typical value ranges for post-void pressures. **A**: type Va error shows that P_{det} after voiding still keeps high levels beyond their TVR while a high post-void residual volume is ruled out. It has a too high P_{ves} but a normal P_{abd}; the reason is that P_{ves} curve became a high level "dead" line due to the signal loss or the urethral catheter dislocation during voiding. In this case, post-void P_{det} is 57 cmH_2O, P_{ves} and P_{abd} are 92 cmH_2O and 35 cmH_2O respectively. **B**: type Vb error shows that P_{det} after voiding still keeps high levels. It has a too low P_{abd} because of the rectal catheter dislocation or the signal loss of P_{abd} tracing during voiding. In this case, post-void P_{det} is 70 cmH_2O, P_{ves} and P_{abd} are 79 cmH_2O and 9 cmH_2O respectively

Another one (type VI error) was that P_{ves} and P_{det} became negative because the urethral catheter was voided with the urine stream during voiding (Fig. 6).

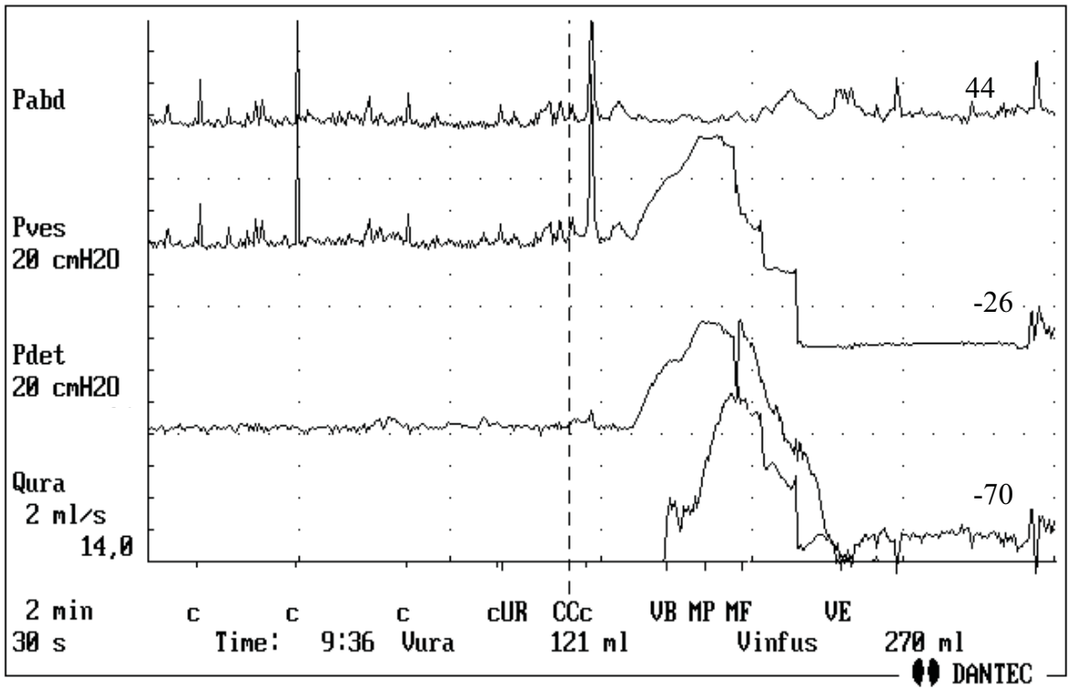


Fig. 6. Type VI error related to typical value ranges for post-void pressures. This type of error shows that P_{ves} and P_{det} become negative after voiding because the urethral catheter has been voided with the urine stream during voiding. In this case, post-void P_{det} is -70 cmH_2O, P_{ves} and P_{abd} are -26 cmH_2O and 44 cmH_2O respectively

3.2 Describing the typical signal patterns

Comparing the various types of signal patterns among P_{ves}, P_{abd} and P_{det} tracings in different cystometric phases, the results were shown in the following tables. From the statistical analyses, we were able to describe typical signal patterns during different cystometric phases. At beginning of filling, 91.8% of traces showed the identical fine structure and microscopic changes between P_{ves} and P_{abd} tracings while P_{det} tracing did not have this fine structure and the microscopic changes. 7.7% of traces showed the different patterns between P_{ves} and P_{abd} due to the problems of signal transmission (Table 5). In the cough tests of initial filling, 74.8% of traces had the equal pressure changes corresponding to the test-coughs between P_{ves} and P_{abd} while P_{det} did not show any change and deflection. 17.5% showed the similar changes between P_{ves} and P_{abd}, which lead to some small biphasic deflections on P_{det} tracing; these biphasic spikes were acceptable. 7.7% had the different changes between P_{ves} and P_{det}, which resulted in the obvious up- or down-deflections; these obvious spikes suggested the problems of pressure transmission (Table 5). In initial phase of filling, only 3.1% of traces showed the macroscopic changes. 0.9% had straining, which was characterized by the identical changes on P_{ves} and P_{abd} tracings but not on P_{det} tracing. 2.2% had rectal contractions, which showed the different changes among P_{ves}, P_{abd} and P_{det}

tracings: a positive wave on the P_{abd} tracing and a negative artifact on the P_{det} tracing but not on P_{ves} tracing (Table 5).

	P_{ves} and P_{abd}			P_{det}			P_{ves} and P_{det}	
	Identical	Similar	Different	Without	Little	Obvious	Identical	Different
	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)
Pattern I: fine structure	534 (91.8)	3 (0.5)	45 (7.7)	534 (91.8)	3 (0.5)	45 (7.7)	-	-
Pattern II: microscopic changes	534 (91.8)	3 (0.5)	45 (7.7)	534 (91.8)	3 (0.5)	45 (7.7)	-	-
Pattern III: cough tests changes	435 (74.8)	102 (17.5)	45 (7.7)	435 (74.8)	102 (17.5)	45 (7.7)	-	-
Pattern IV: macroscopic changes								
a: straining (no=5)	4 (80)	1 (20)	0 (0)	4 (80)	1 (20)	0 (0)	-	-
b: detrusor overactivity (no=0)	0	0	0	0	0	0	0	0
c: rectal contractions (no=13)	0 (0)	0 (0)	13 (100)	0 (0)	0 (0)	13 (100)	0 (0)	13 (100)

Table 5. Comparing the various of signal patterns among P_{ves}, P_{abd} and P_{det} tracings at beginning of filling in 582 cystometries

During filling phase, 98.3% of traces showed the identical fine structure and microscopic changes between P_{ves} and P_{abd} while P_{det} trace did not have this fine structure and the microscopic changes. 1.5% of traces showed the different patterns between P_{ves} and P_{abd} due to the problems of signal transmission (Table 6). In the cough tests at regular intervals during filling, 67.0% of traces had the equal pressure changes corresponding to the test-coughs between P_{ves} and P_{abd} while P_{det} did not show any changes and deflections. 31.5% showed the similar changes between P_{ves} and P_{abd}, which lead to some biphasic deflections on P_{det} tracing; these biphasic spikes were acceptable. 1.5% had the different changes between P_{ves} and P_{det}, which resulted in the obvious up- or down- deflections; these obvious spikes suggested the unequal pressure transmission (Table 6). There were various types of typical macroscopic changes occurred during filling. 8.3% of 582 traces showed straining. 91.7% of 48 straining traces were characterized by the identical changes on P_{ves} and P_{abd} tracings but not on P_{det} tracing; but 8.3% showed the changes on P_{det} tracing due to the different transmission to P_{ves} and P_{abd} corresponding to straining. 33.7% of 582 traces had detrusor overactivity, which showed that single or multiple unstable waves recorded on P_{ves} and P_{det} tracings but not on P_{abd} tracing. 17.4% of 582 had rectal activity, which showed single or multiple rectal contractions recorded on P_{abd} tracing; and the changes among P_{ves}, P_{abd} and P_{det} tracings were different: a positive wave on the P_{abd} tracing and a negative artifact on the P_{det} tracing but not on P_{ves} tracing (Table 6).

	P_{ves} and P_{abd}			P_{det}			P_{ves} and P_{det}	
	Identical	Similar	Different	Without	Little	Obvious	Identical	Different
	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)
Pattern I: fine structure	572 (98.3)	1 (0.2)	9 (1.5)	572 (98.3)	1 (0.2)	9 (1.5)	-	-
Pattern II: microscopic changes	572 (98.3)	1 (0.2)	9 (1.5)	572 (98.3)	1 (0.2)	9 (1.5)	-	-
Pattern III: cough tests changes	390 (67.0)	183 (31.5)	9 (1.5)	390 (67.0)	183 (31.5)	9 (1.5)	-	-
Pattern IV: macroscopic changes								
a: straining (no=48)	44 (91.7)	4 (8.3)	0 (0)	44 (91.7)	4 (8.3)	0 (0)	-	-
b: detrusor overactivity (no=196)	0 (0)	0 (0)	196 (100)	0 (0)	0 (0)	196 (100)	196 (100)	0 (0)
c: rectal contractions (no=101)	0 (0)	0 (0)	101 (100)	0 (0)	0 (0)	101 (100)	0 (0)	101 (100)

Table 6. Comparing the various of signal patterns among P_{ves}, P_{abd} and P_{det} tracings during filling in 582 cystometries

Before voiding, 94.0% of traces had the equal rises in P_{ves} and P_{abd} corresponding to cough tests; 1.9% showed the small biphasic spikes; and 4.1% had the significant spikes, which suggested the different pressure transmission (Table 7).

	P_{ves} and P_{abd}			P_{det}		
	Identical	Similar	Different	Without	Little	Obvious
	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)
Pattern I: fine structure (after voiding)	531 (91.2)	5 (0.9)	46 (7.9)	531 (91.2)	5 (0.9)	46 (7.9)
Pattern III: cough tests changes						
a: before voiding	547 (94.0)	11 (1.9)	24 (4.1)	547 (94.0)	11 (1.9)	24 (4.1)
b: after voiding	509 (87.5)	24 (4.1)	49 (8.4)	509 (87.5)	24 (4.1)	49 (8.4)

Table 7. Comparing the various of signal patterns among P_{ves}, P_{abd} and P_{det} tracings before and after voiding in 582 cystometries

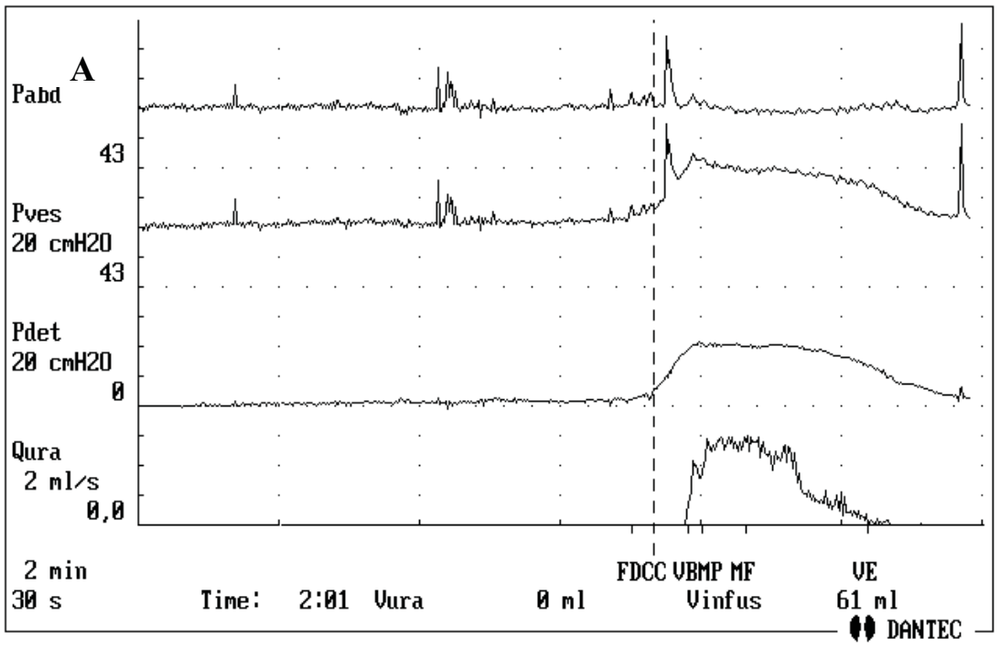
During voiding, 91.2% of traces still kept the "live" signal on P_{ves} and P_{abd} tracings, which had the same fine structure and microscopic changes; but 7.9% showed the "dead" signals on

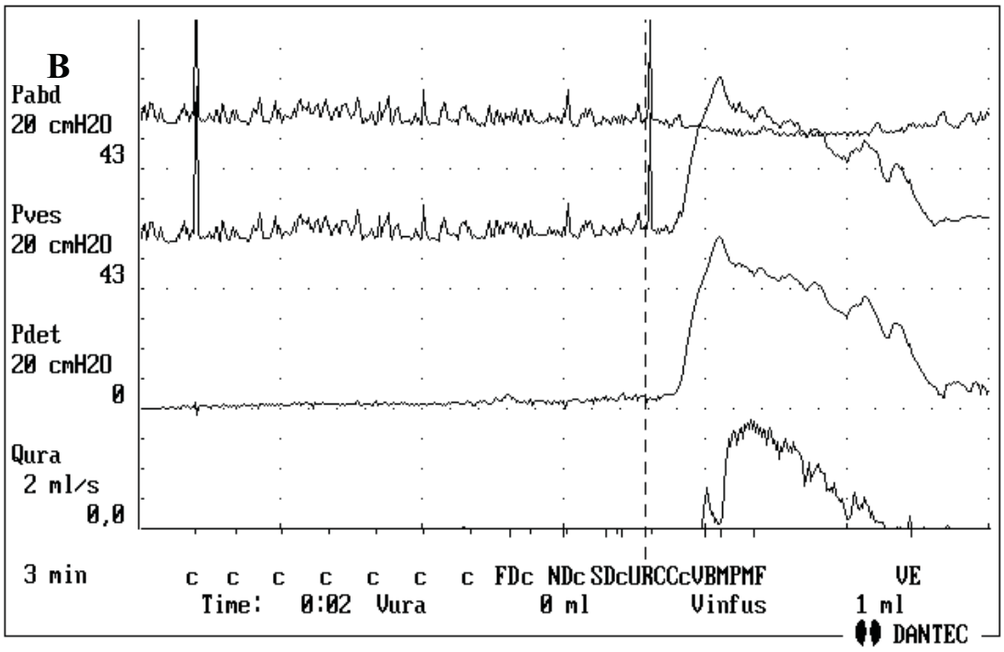
P_{ves} or P_{abd} tracing due to various causes, which showed the different fine structures and microscopic changes (Table 8). Also, there were several types of typical macroscopic changes occurred during voiding. 95.2% of traces showed the identical and simultaneous increase and decrease on P_{ves} and P_{det} when detrusor contracted to void; 4.8% had the atypical patterns due to urethral catheter dislocation or signal loss of P_{ves} during voiding. However, there were three special patterns of detrusor contraction in our data: 0.9% after-contraction, 3.4% fluctuation contraction and 3.1% unstable detrusor voiding. The traces with after-contraction showed that P_{ves} and P_{det} increased after uroflow tracing; ones with fluctuation contraction showed that P_{ves} and P_{det} tracings fluctuated corresponding to the simultaneous changes of uroflow tracing; ones with unstable detrusor voiding showed that P_{ves} and P_{det} increased rapidly before uroflow tracing, then fell suddenly as soon as flow started. 53.3% of 582 traces showed the different degrees of straining during voiding. 71.6% of 310 straining traces were characterized by the identical changes on P_{ves} and P_{abd} tracings but not on P_{det} tracing. 28.4% showed various changes on P_{det} tracing, which were spikes and dips on P_{det} curve due to the different transmission to P_{ves} and P_{abd} corresponding to straining. 2.1% of 582 traces had rectal contractions during voiding, which lead to different patterns between P_{ves} and P_{det}, and were characterized by some dips on P_{det} curve. 15.3% of 582 traces showed the different degrees of relaxation of pelvic floor during voiding, which were characterized by the different degrees of decreases on P_{abd} curve, and resulted in the similar or identical changes on P_{ves} and P_{det} curves (Table 8).

	P_{ves} and P_{abd}			P_{det}			P_{ves} and P_{det}	
	Identical	Similar	Different	Without	Little	Obvious	Identical	Different
	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)	no (%)
Pattern I: fine structure	531 (91.2)	5 (0.9)	46 (7.9)	531 (91.2)	5 (0.9)	46 (7.9)	-	-
Pattern II: microscopic changes	531 (91.2)	5 (0.9)	46 (7.9)	531 (91.2)	5 (0.9)	46 (7.9)	-	-
Pattern IV: macroscopic changes								
a: detrusor contraction (no=582)	0 (0)	0 (0)	582 (100)	0 (0)	0 (0)	582 (100)	554 (95.2)	28 (4.8)
b: straining (no=310)	220 (71.0)	2 (0.6)	88 (28.4)	220 (71.0)	2 (0.6)	88 (28.4)	-	-
c: rectal contractions (no=12)	0 (0)	0 (0)	12 (100)	0 (0)	0 (0)	12 (100)	0 (0)	12 (100)
d: relaxation (no=89)	0 (0)	0 (0)	89 (100)	0 (0)	89 (100)	0 (0)	89 (100)	0 (0)

Table 8. Comparing the various of signal patterns among P_{ves}, P_{abd} and P_{det} tracings during voiding in 582 cystometries

After voiding, 91.2% of traces had the same fine structure between P_{ves} and P_{abd} tracings, which were "live" signal; but 7.9% showed the "dead" signals on P_{ves} or P_{abd} tracings due to various artifacts occurred during voiding. These traces had the different fine structures and microscopic changes on P_{ves} and P_{abd} tracings during and after voiding. After voiding, 87.5% of traces had the equal pressure rises in P_{ves} and P_{abd} corresponding to cough tests; 4.1% showed some acceptable biphasic spikes on P_{det} tracing; and 8.4% did obvious spikes suggesting the problems of signal quality during voiding (Table 7).





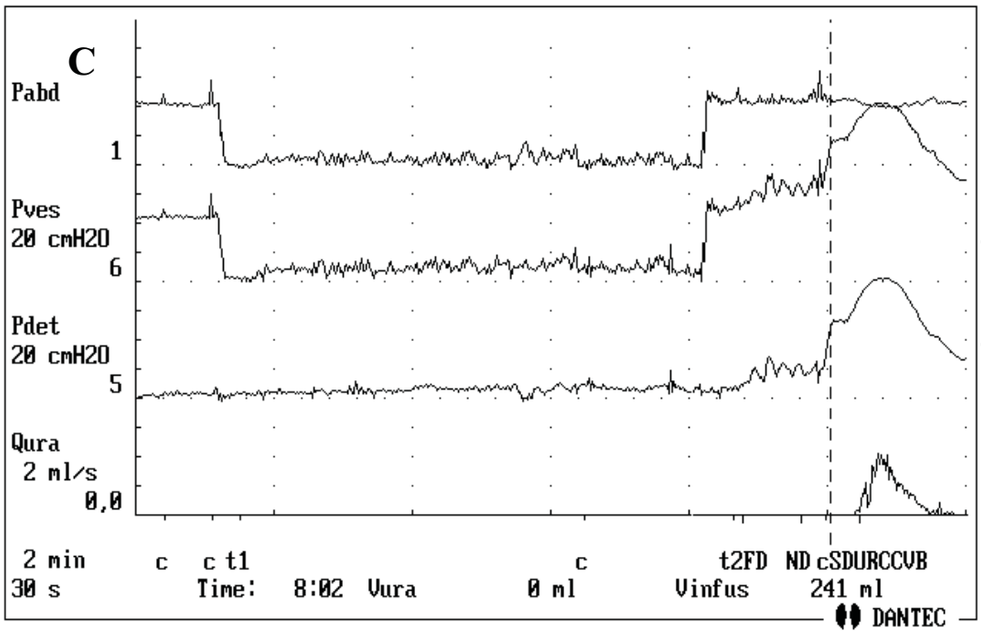


Fig. 7. The fine structure (pattern I) and microscopic changes (pattern II) of signals. **A**: there are the same fine structures on P_{ves} and P_{abd} tracings at all stages of investigation, which show the "live" signals with some minimal variations (noise); but P_{det} tracing does not have fine structure. **B**: fine structure becomes the stronger signal activity called microscopic changes with patient's breathing and talking; P_{ves} and P_{abd} tracings show the identical microscopic changes, but P_{det} tracing has no change. **C**: P_{ves} and P_{abd} tracings keep identical changes with patient's moving or position change, P_{det} tracing does not show obvious changes

On the base of above-mentioned results, we can describe TSP of pressures during cystometry from four gradations. At beginning of and during filling, P_{ves} and P_{abd} tracings have the identical fine structure, which showed the "live" signals with some minimal variations (noise). The fine structure become the stronger signal activity corresponding to the patient's breathing, talking or moving, which means that there are the same microscopic changes on P_{det} and P_{abd} tracings. P_{det} tracing dose not show any fine structure and microscopic changes (Fig. 7a, b and c). When the cough tests are undergone at beginning of filling or at regular intervals during filling, the equal major pressure changes on P_{ves} and P_{abd} tracings are produced corresponding to the test-coughs; P_{det} tracing dose not show any changes, or at most, has some small biphasic spikes; these points suggest a high signal quality (Fig. 8a, 8b). There may be several types of typical macroscopic signal changes. Straining is characterized by the identical pressure changes on P_{ves} and P_{abd} tracings in response to strains but not on P_{det} tracing (Fig. 9a). Detrusor overactivity shows that single or multiple unstable waves due to detrusor contractions are recorded on P_{ves} and P_{det} tracings but not on P_{abd} tracing (Fig. 9b). Rectal activity, which results from single or multiple rectal contractions, is characterized by the different changes among P_{ves}, P_{abd} and P_{det} tracings: a positive wave on the P_{abd} tracing and a negative artifact on the P_{det} tracing but not on P_{ves} tracing (Fig. 9c). Before voiding, P_{ves} and P_{abd} have the equal response to the cough tests; and there are may be some biphasic spikes on P_{det} tracing but without obvious spikes (Fig. 8b). During voiding, P_{ves} and P_{abd} tracings still keep the "live" signals, and show the same fine structure and microscopic changes; but P_{det} tracing does not have (Fig. 10).

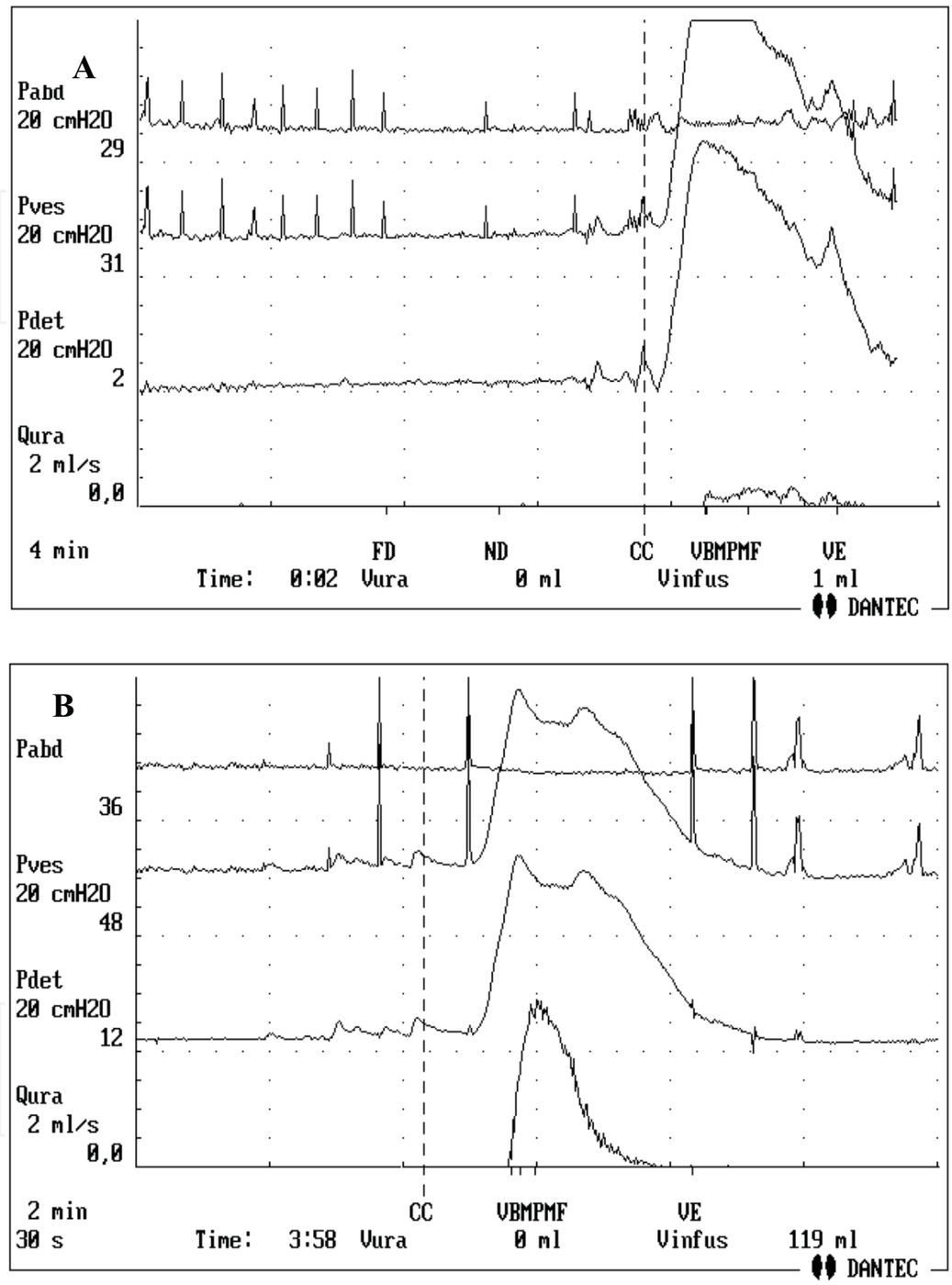
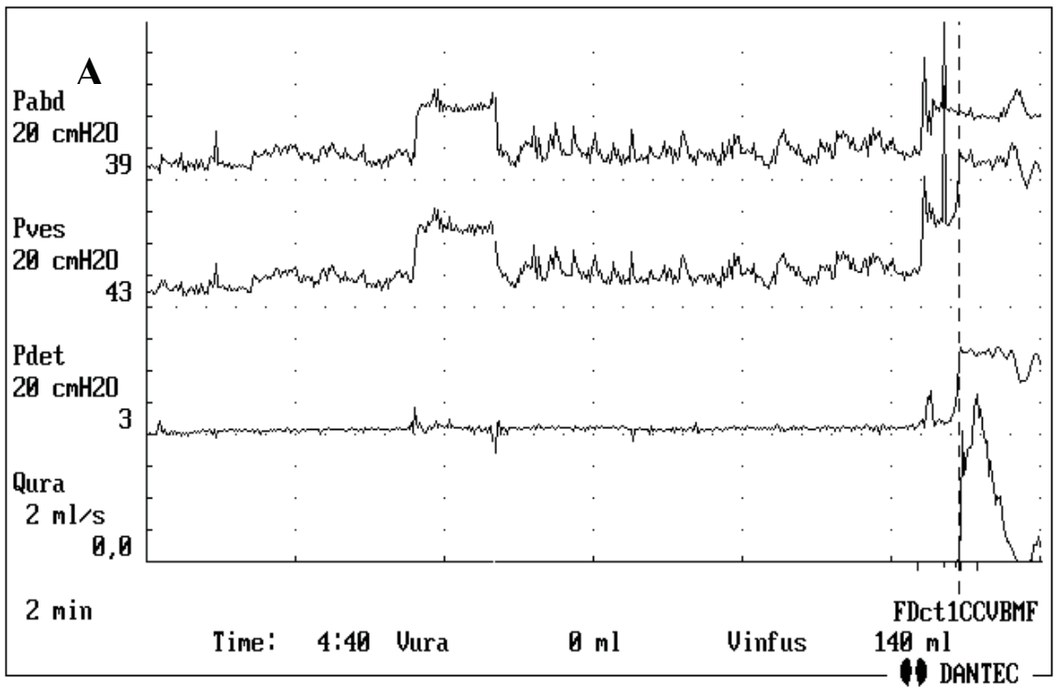
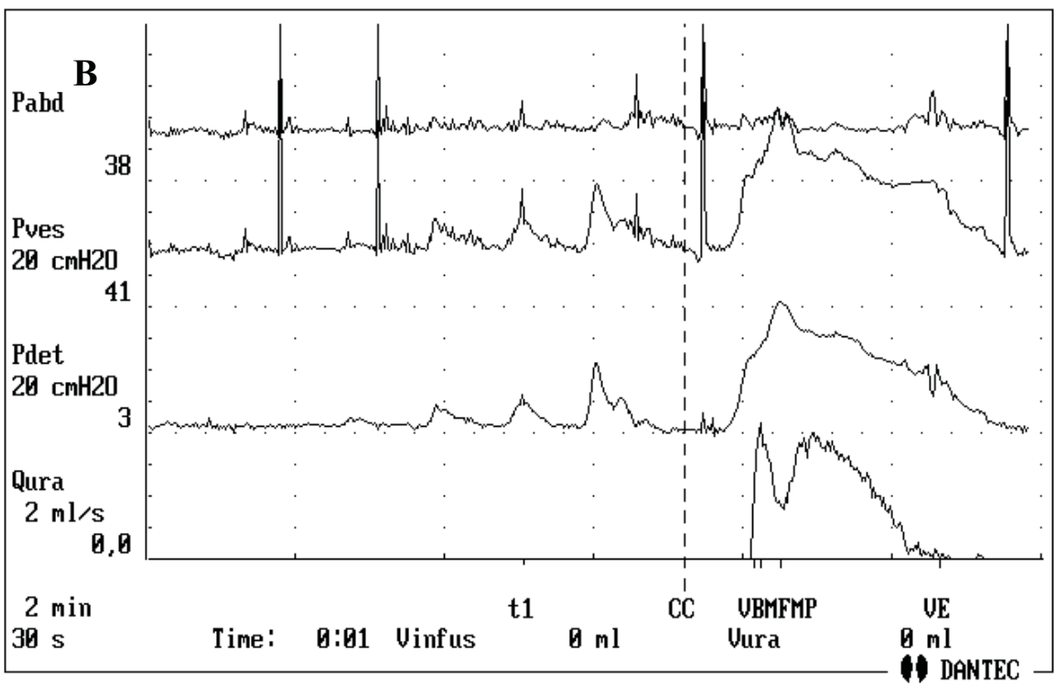


Fig. 8. The major changes of signals corresponding to cough tests (pattern III). **A**: P_{ves} and P_{abd} tracings show equal pressure changes corresponding to cough tests at beginning of filling and during filling at regular intervals; there is no obvious changes on P_{det} tracing. **B**: P_{ves} and P_{abd} tracings show equal pressure changes corresponding to cough tests before and after voiding; there is no obvious changes on P_{det} tracing


A
Pabd
20 cmH2O
39
Pves
20 cmH2O
43
Pdet
20 cmH2O
3
Qura
2 ml/s
0,0
2 min
FDct1CCVBMF
Time: 4:40 Vura 0 ml Vinfus 140 ml
DANTEC


B
Pabd
38
Pves
20 cmH2O
41
Pdet
20 cmH2O
3
Qura
2 ml/s
0,0
2 min
30 s
t1
CC
VBMFMP
VE
Time: 0:01 Vinfus 0 ml Vura 0 ml
DANTEC

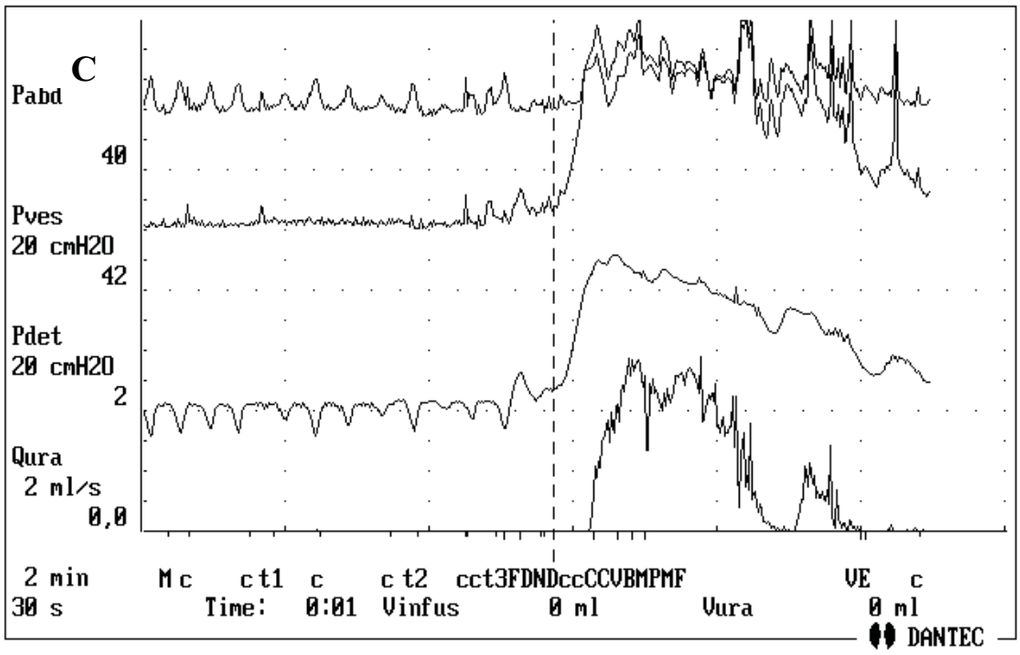


Fig. 9. The macroscopic changes of signals during filling: straining, detrusor overactivity and rectal contractions (pattern IV). **A**: straining is characterized by the identical signal changes on P_{ves} and P_{abd} tracings corresponding to strains but not on P_{det} tracing. **B**: detrusor overactivity shows that the unstable waves on P_{ves} and P_{det} tracings but not on P_{abd} tracing. **C**: rectal contractions are characterized by the different changes among P_{ves}, P_{abd} and P_{det} tracings: the positive waves on P_{abd} tracing and the negative dips on P_{det} tracing but not on P_{ves} tracing

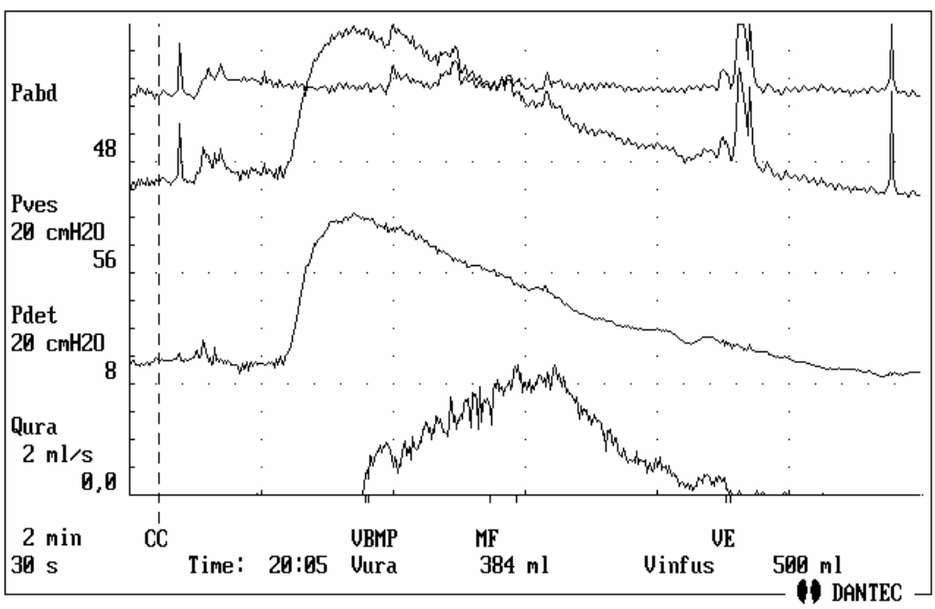
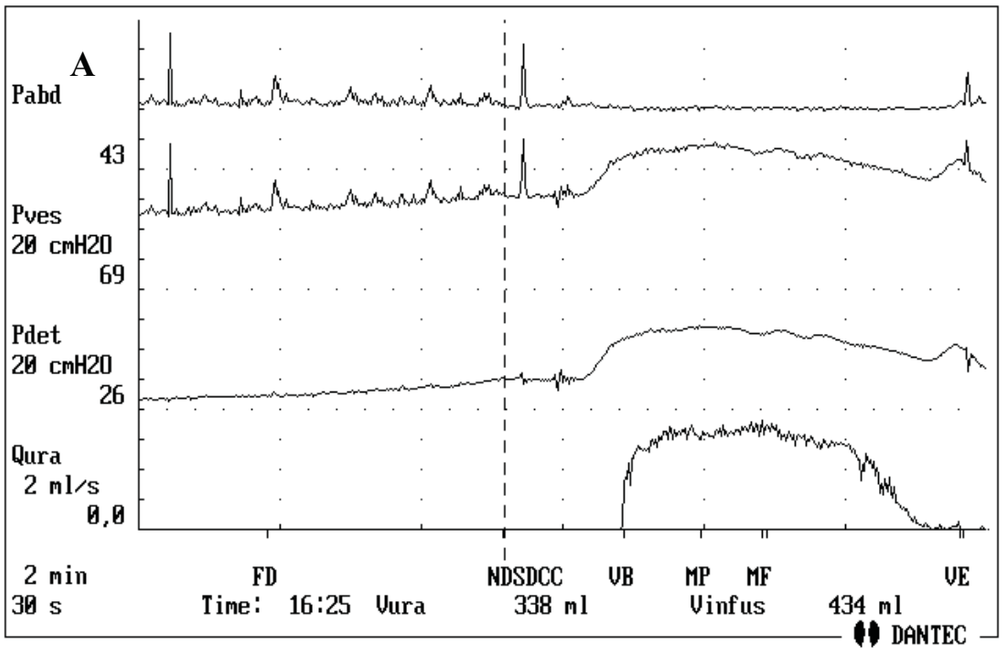
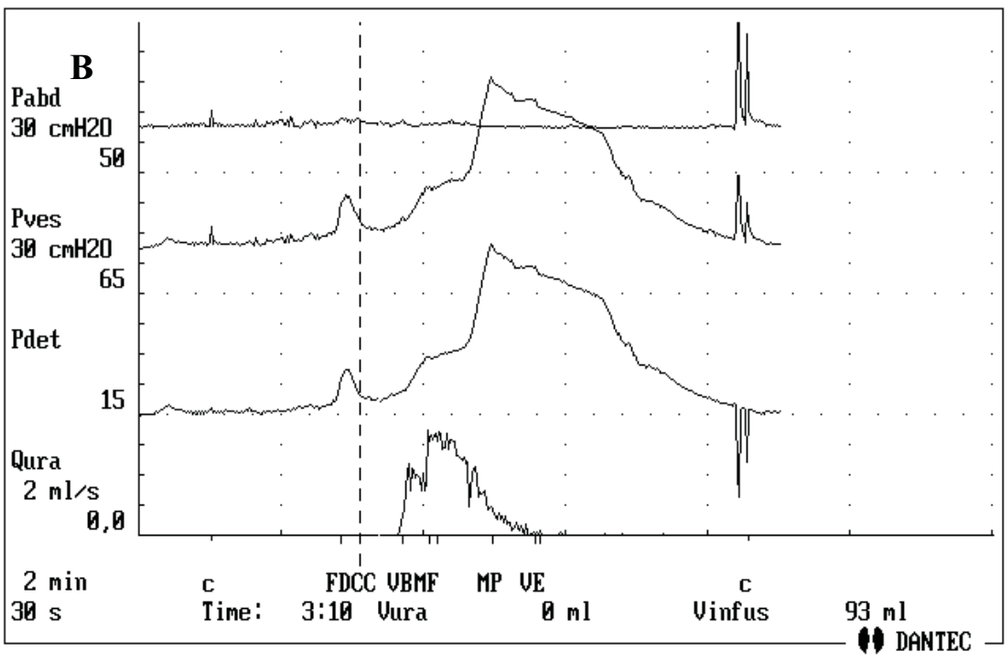


Fig. 10. The fine structures and microscopic changes during and after voiding (pattern I and II). During and after voiding, P_{ves} and P_{abd} tracings still keep the "live" signals, and show the same fine structure and microscopic changes; but P_{det} tracing does not have


A
Pabd
43
Pves
20 cmH2O
69
Pdet
20 cmH2O
26
Qura
2 ml/s
0,0
2 min
30 s
FD
NDSDCC VB MP MF VE
Time: 16:25 Vura 338 ml Vinfus 434 ml
DANTEC


B
Pabd
30 cmH2O
50
Pves
30 cmH2O
65
Pdet
15
Qura
2 ml/s
0,0
2 min
30 s
c
FDCC VBMF MP VE
c
Time: 3:10 Vura 0 ml Vinfus 93 ml
DANTEC

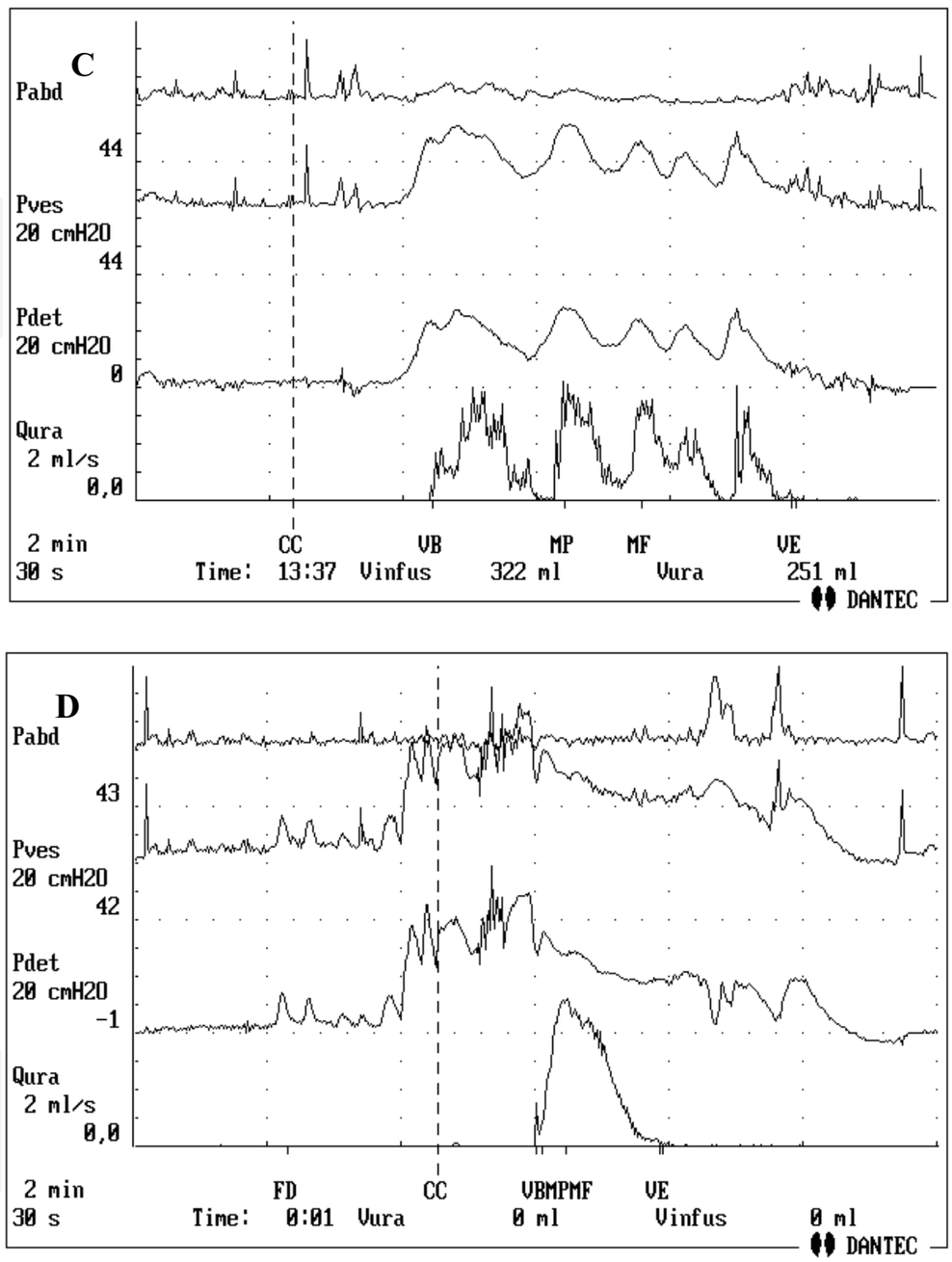
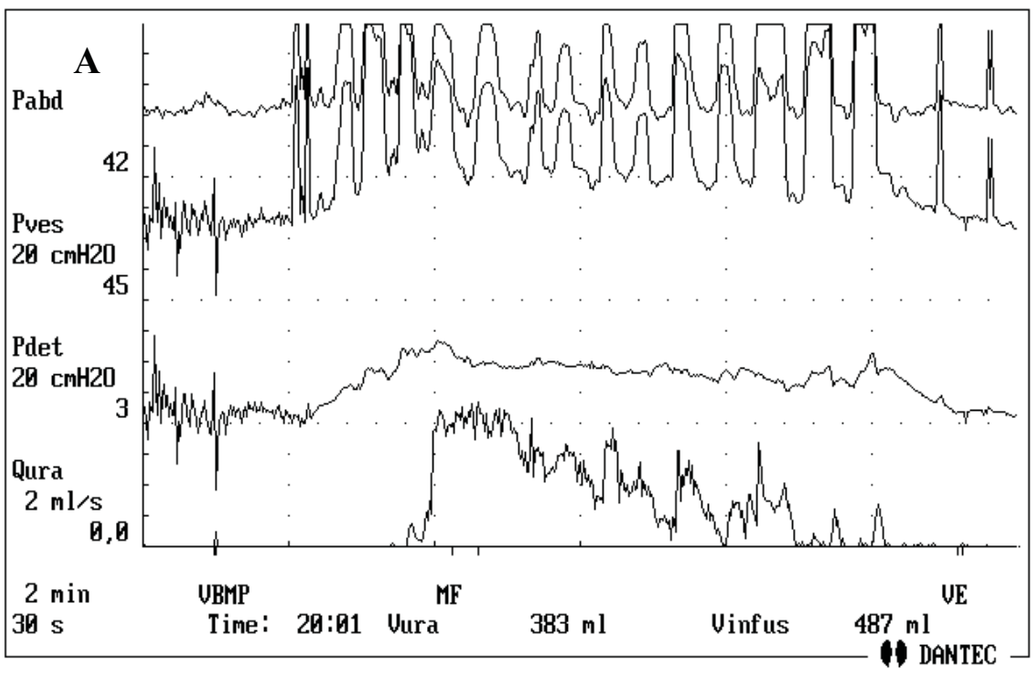


Fig. 11. The macroscopic changes of signals during voiding (pattern IV): the different patterns of detrusor contraction. **A**: typical pattern: typical detrusor contraction shows the smooth and identical pressure increase and decrease on P_{ves} and P_{det} tracings corresponding to the simultaneous changes on uroflow tracing. **B**: special pattern: after-contraction is characterized by that P_{ves} and P_{det} increase after uroflow tracing. **C**: special pattern: fluctuation contraction shows that P_{ves} and P_{det} tracings fluctuate corresponding to the simultaneous changes of uroflow tracing. **D**: special pattern: unstable detrusor voiding shows that P_{ves} and P_{det} increase rapidly before uroflow tracing, then fall suddenly when flow starts

There may be several types of typical macroscopic changes occurred during voiding. Typical detrusor contraction shows identical and simultaneous pressure increase and decrease on P_{ves} and P_{det} tracings (Fig. 11a); but there are some special patterns of detrusor contraction, for example, after-contraction, fluctuation contraction and unstable detrusor voiding. After-contraction is characterized by that Pves and Pdet increase after uroflow tracing (Fig.11b); fluctuation contraction shows that Pves and Pdet tracings fluctuate corresponding to the simultaneous changes of uroflow tracing (Fig. 11c); unstable detrusor voiding shows that Pves and Pdet increase acutely before uroflow tracing, then fall suddenly as soon as flow starts (Fig. 11d). Straining is characterized by the identical pressure changes on Pves and Pabd tracings but not on Pdet tracing (Fig. 12a). Rectal contractions lead to different patterns between Pves and Pdet, and are characterized by some dips on Pdet curve (Fig. 12b). Relaxation of pelvic floor is characterized by the pressure decreases of different degrees on Pabd tracing, and the changes on Pves and Pdet tracings are similar or identical (Fig. 12c). After voiding, Pves and Pabd tracings still have the same fine structure and microscopic changes with "live" signal, and keep the equal response to the cough tests; they indicate that there is a good signal quality during voiding (Fig. 8b, Fig. 10).



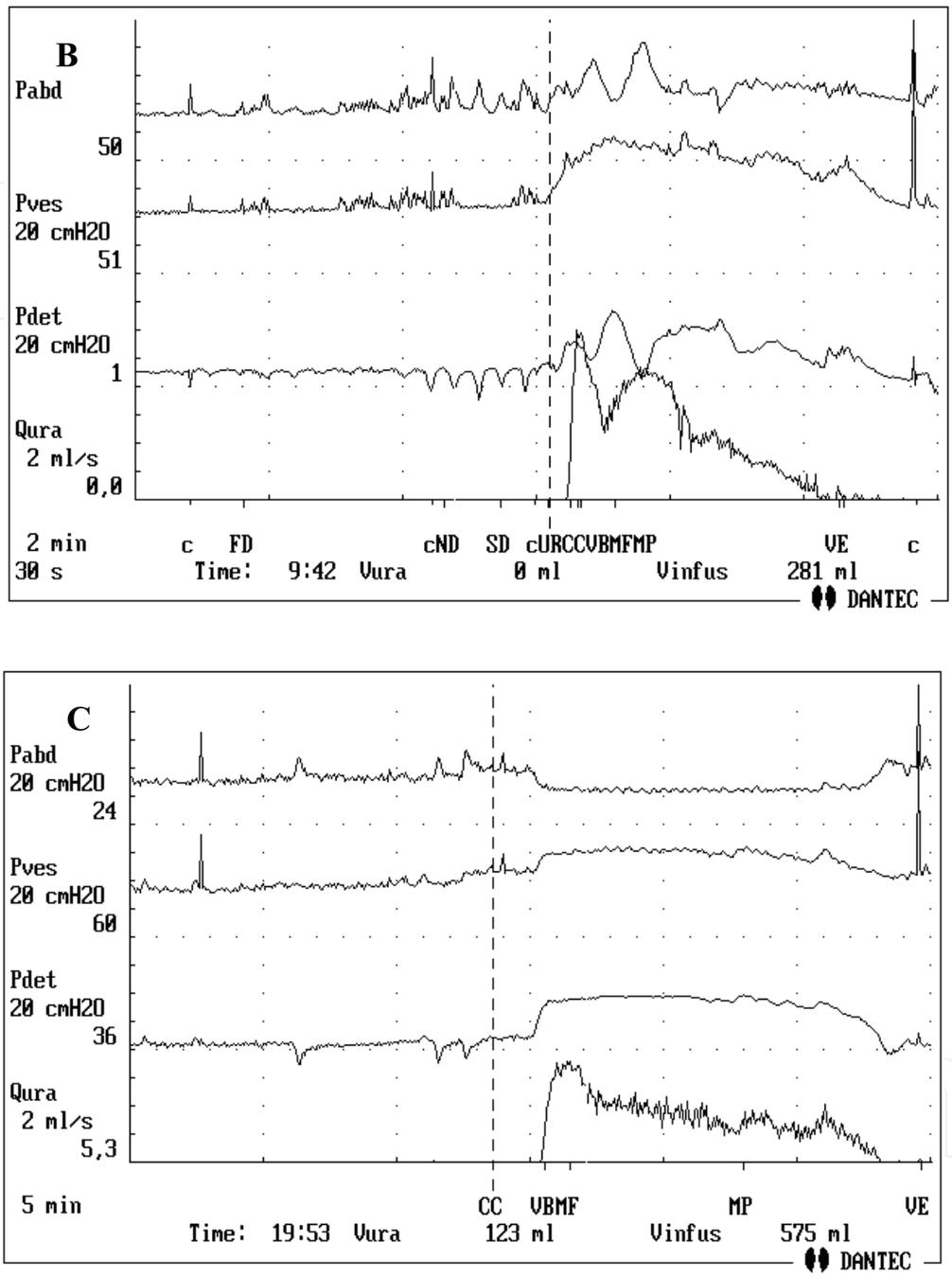


Fig. 12. The macroscopic changes of signals during voiding (pattern IV): straining, rectal contractions and relaxation of pelvic floor. **A**: straining is characterized by the identical pressure changes on P_{ves} and P_{abd} tracings but not on P_{det} tracing. **B**: rectal contractions lead to different patterns between P_{ves} and P_{det}, and are characterized by two dips on P_{det} curve. **C**: relaxation of pelvic floor shows the pressure decreases of different degrees on P_{abd} tracing, and the changes on P_{ves} and P_{det} tracings are similar or identical

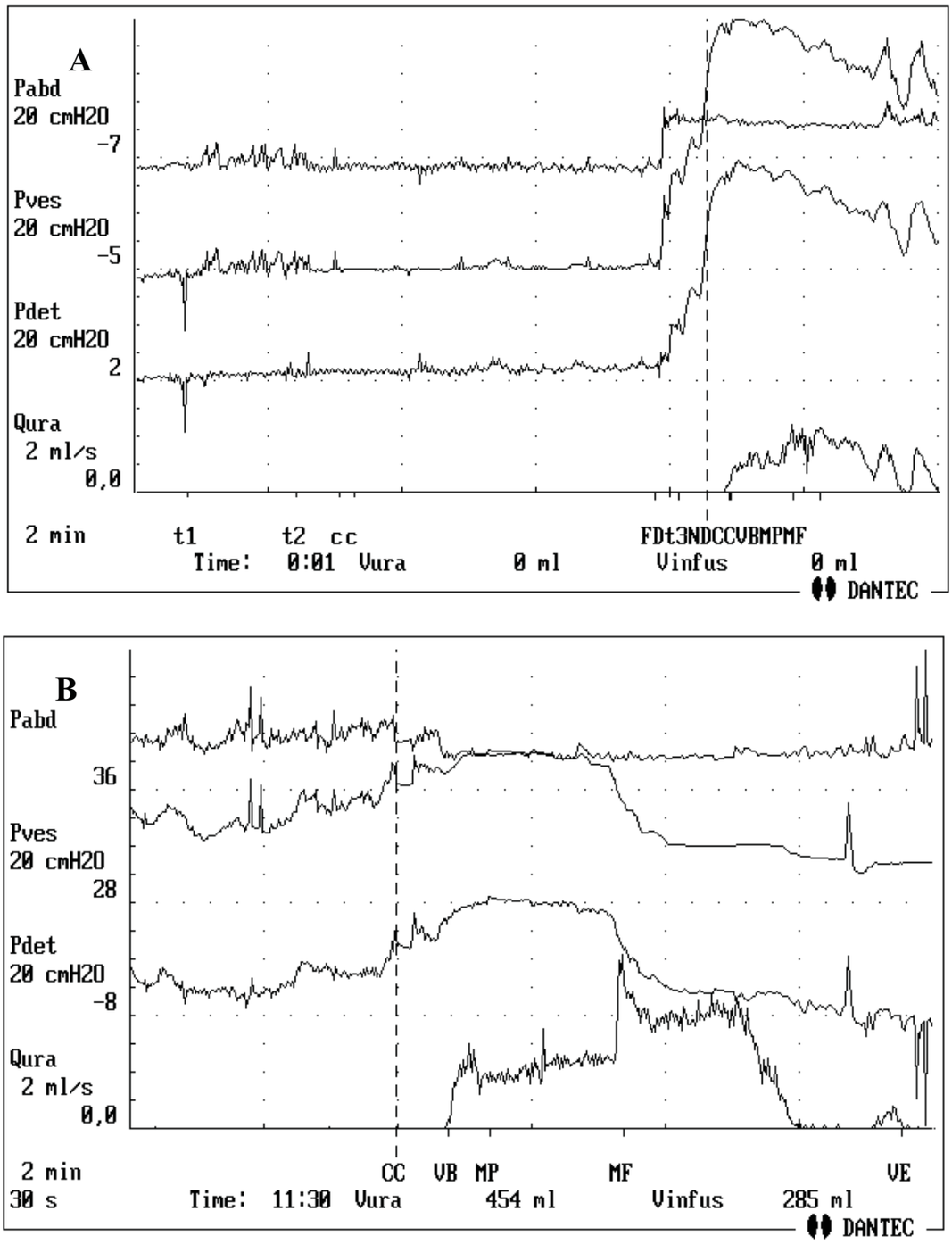
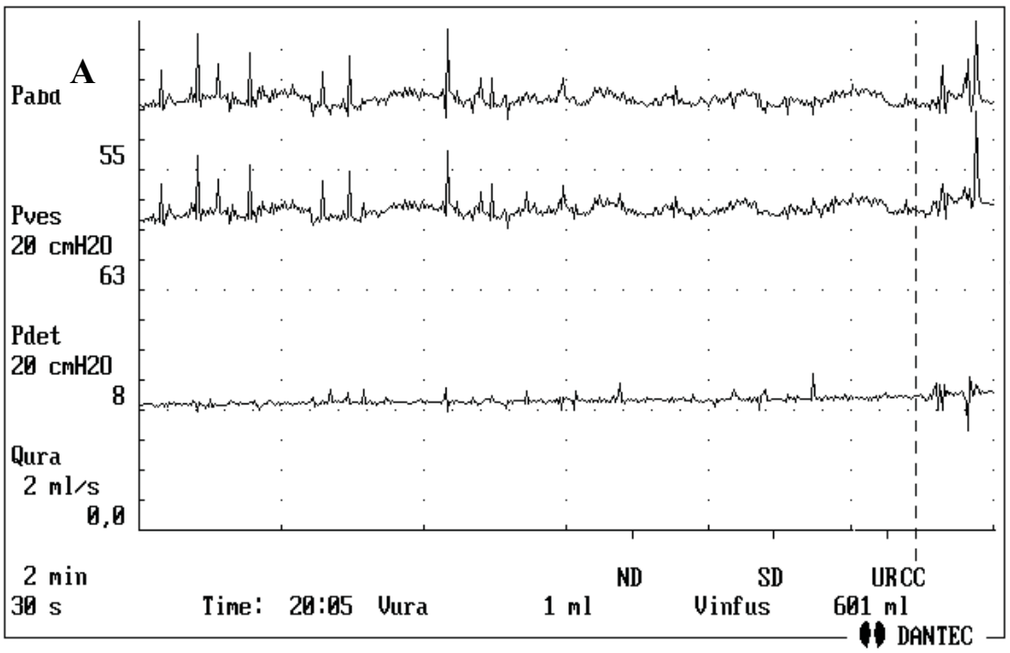
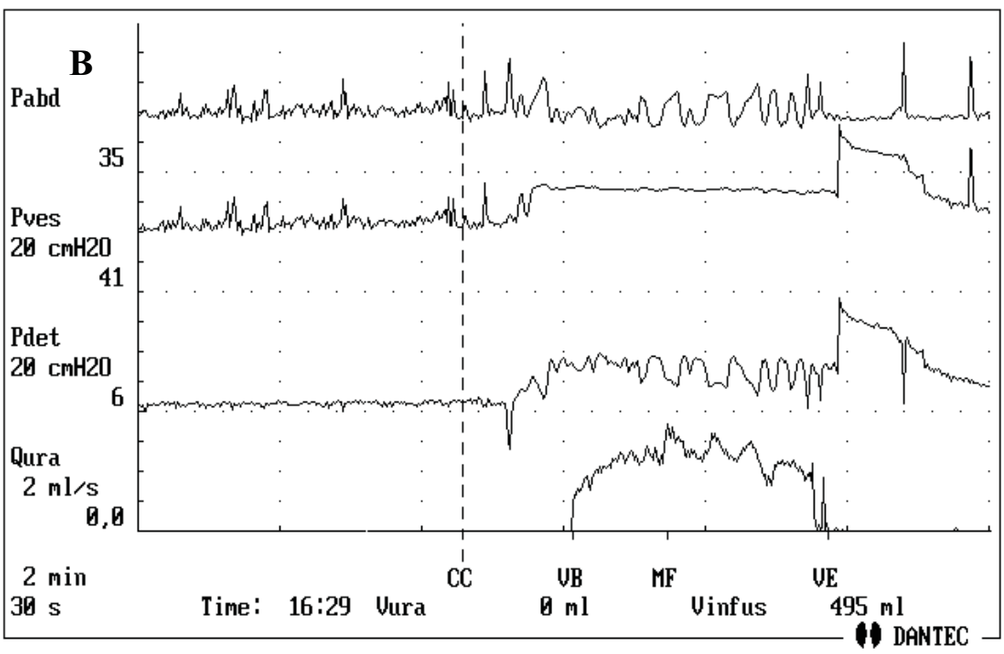


Fig. 13. The errors and artifacts related to fine structure and minor changes. **A**: fine structure and minor changes on P_{ves} tracing disappeared during filling phase, suggesting the problems of signal quality. **B**: fine structure and minor changes on P_{ves} tracing disappeared during voiding phase, suggesting the problems of signal quality or other artifacts occurred during voiding


A
Pabd
55
Pves
20 cmH2O
63
Pdet
20 cmH2O
8
Qura
2 ml/s
0,0
2 min
30 s
ND
SD
URCC
Time: 20:05 Vura 1 ml Vinfus 601 ml
DANTEC


B
Pabd
35
Pves
20 cmH2O
41
Pdet
20 cmH2O
6
Qura
2 ml/s
0,0
2 min
30 s
CC
VB
MF
VE
Time: 16:29 Vura 0 ml Vinfus 495 ml
DANTEC

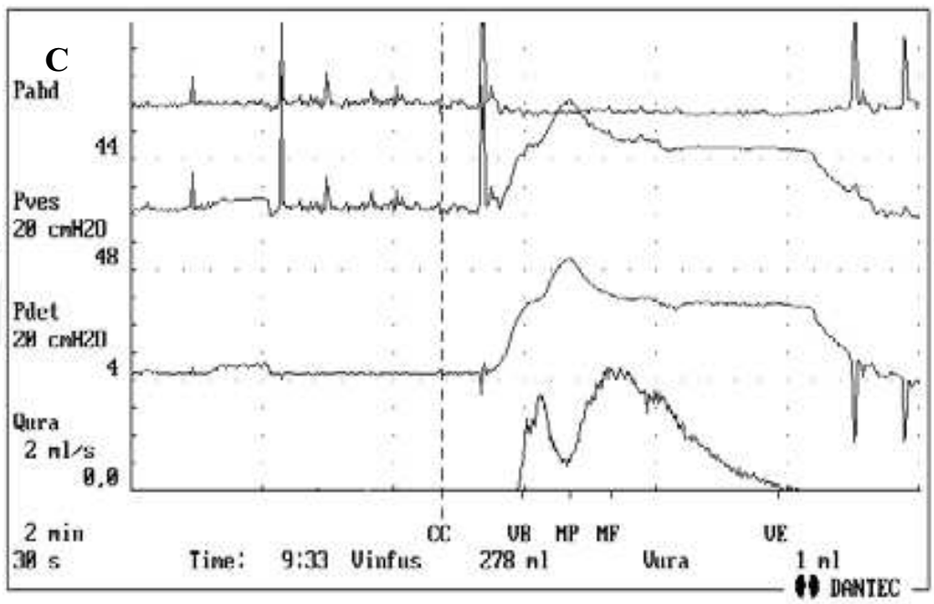


Fig. 14. The errors and artifacts caused by the different responses to cough tests between P_{ves} and P_{abd} tracings during different phases. **A**: there are some up- or down deflections and biphasic spikes on P_{det} tracing due to the different pressure transmissions between P_{ves} and P_{abd} tracings during filling. **B**: P_{ves} tracing does not respond to cough-test before voiding, then a P_{ves} tracing with "dead" signals appear during voiding. **C**: P_{ves} tracing does not respond to cough-tests after voiding, this suggests the signal loss on P_{ves} tracing during voiding

According to above-mentioned TSP, we gave some examples for atypical signal patterns or artifacts to indicate the role and significance of TSP in quality control during cystometry. As the indicator of "live" signals, fine structure and minor changes should exist at all stages of investigation; their disappearance indicated the certain problems of signal quality. Fig. 13a and 13b showed that fine structure and minor changes on P_{ves} tracing disappeared during filling and voiding phases respectively. Cough test is a powerful tool to examine the signal quality during different cystometric phases; the different response to test-coughs between P_{ves} and P_{abd} tracings suggested the problems of pressure transmission and other artifacts. Fig. 14a showed some deflections and biphasic spikes on P_{det} tracing due to the different pressure transmissions during filling; Fig.14b showed that P_{ves} did not respond to cough-tests before voiding, then a P_{ves} tracing with "dead" signal appeared during voiding; Fig.14c showed that P_{ves} did not respond to cough-tests after voiding, this suggested the signal loss on P_{ves} tracing during voiding. Therefore, the cough tests before and after voiding are especially important for signal quality control during voiding. The different response to straining between P_{ves} and P_{abd} can lead to some artifacts on P_{det} tracing; Fig.15a showed this type of artifact occurred during filling; Fig.15b showed some spikes on P_{det} tracing due to the different transmissions to straining during voiding. The sudden pressure drops on both P_{ves} and P_{det} tracings often suggest urethral catheter loss during voiding (Fig.16). The scale of signal is the base of TSP recognition; a changed scale often leads a wrong impression. Fig.17 suggested that an enhanced scale on P_{det} lead to an obvious fine structure on P_{det} tracing, which was not equal to the subtraction between P_{ves} and P_{abd} tracings.

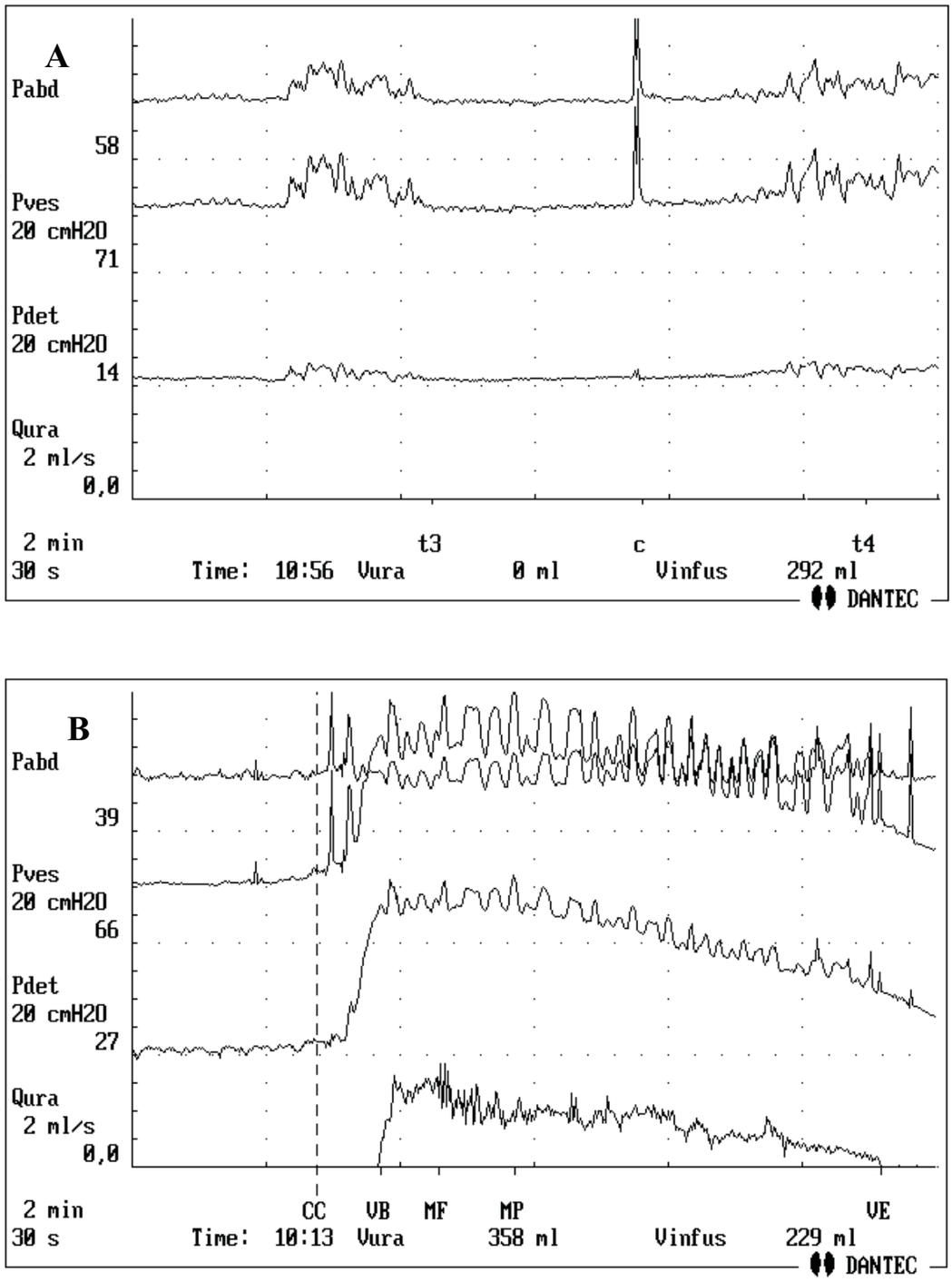


Fig. 15. The errors and artifacts resulted from the different responses to straining between P_{ves} and P_{abd} tracings. **A**: there are some artifacts on P_{det} tracing due to the different transmission to straining during filling. **B**: some spikes on P_{det} tracing due to the different transmission to straining during voiding

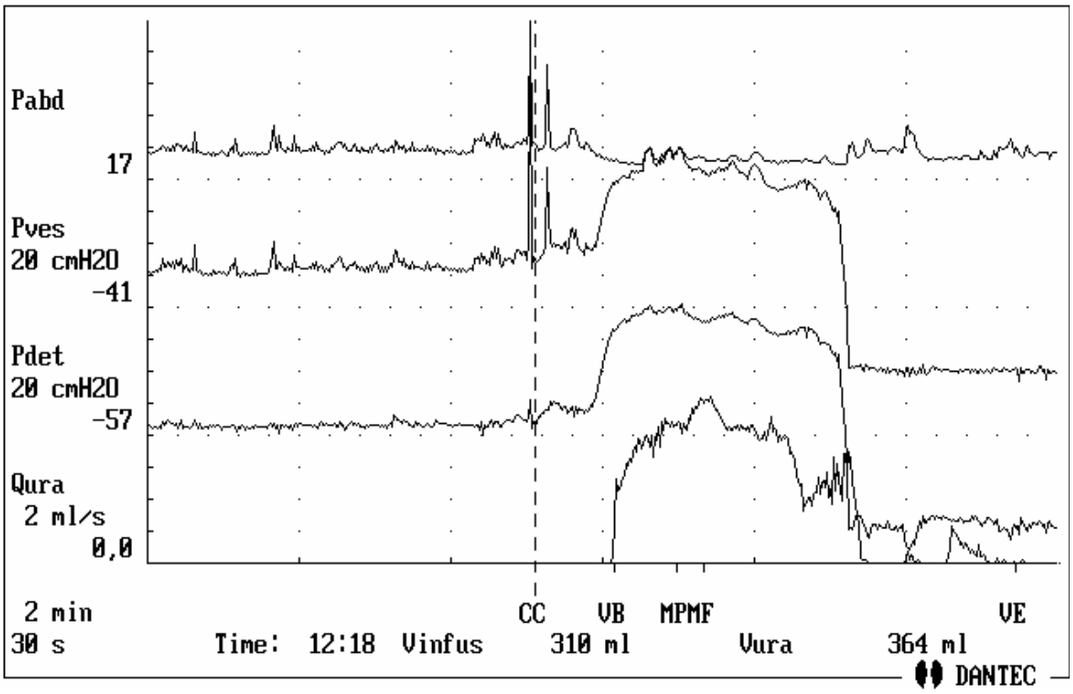


Fig. 16. The sudden drops on both P_{ves} and P_{det} tracings suggest urethral catheter loss during voiding

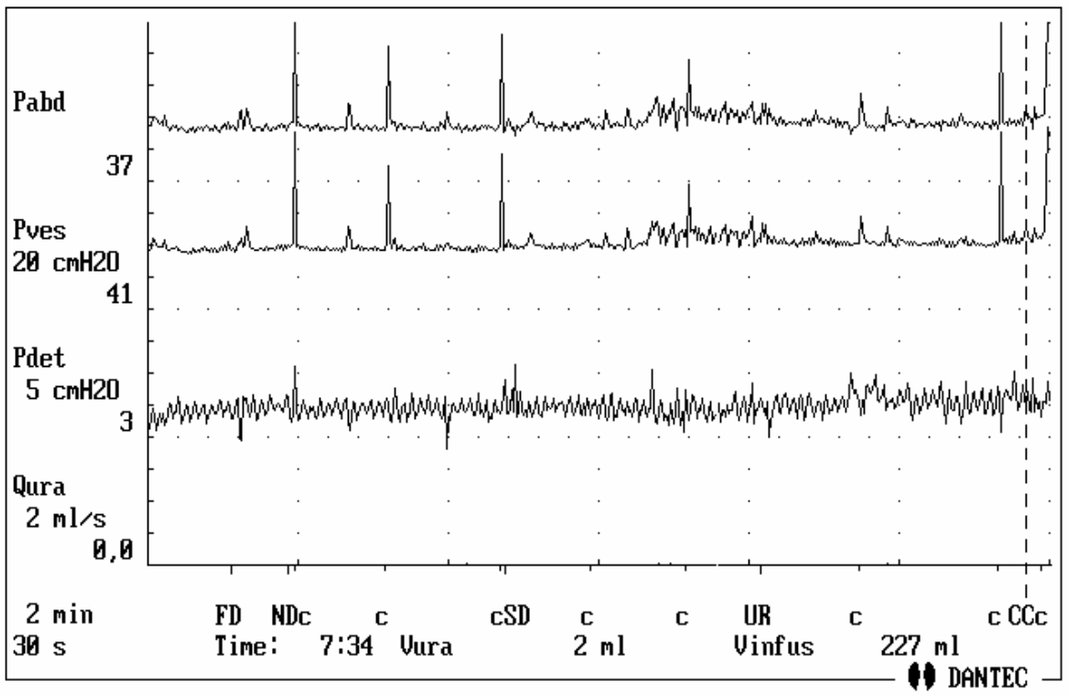


Fig. 17. The artifacts related to the signal scale: a changed scale often leads a wrong impression. This case shows that an enhanced scale on P_{det} leads to an obvious fine structure on P_{det} tracing, which is not equal to the subtraction between P_{ves} and P_{abd} tracings

3.3 Retrospective quality control of urodynamic data

582 (96.0%) of 606 pressure-flow traces were included and analyzed; 24 (4.0%) traces had to be discarded due to non-interpretable and non-correctional artifacts.

3.3.1 Artifacts during filling phase

4.5% of 582 traces had the negative initial resting P_{det} (Fig. 2); and 1.4% had over high initial resting P_{det} (Fig. 3). 31.5% of 582 traces showed the biphasic spikes, and 1.5% showed obvious deflections (14a). 1.6% of 582 traces showed the phasic loss of pressure signals; 1.0% showed stepwise changes on P_{ves} or P_{abd} tracings.

3.3.2 Artifacts during voiding phase

81.8% (476/ 582) traces showed obvious artifacts of Q_{max} (Fig. 18a, b); 23.1% of 476 traces were corrected for the location of Q_{max} on uroflow tracing (Fig. 19a, b).

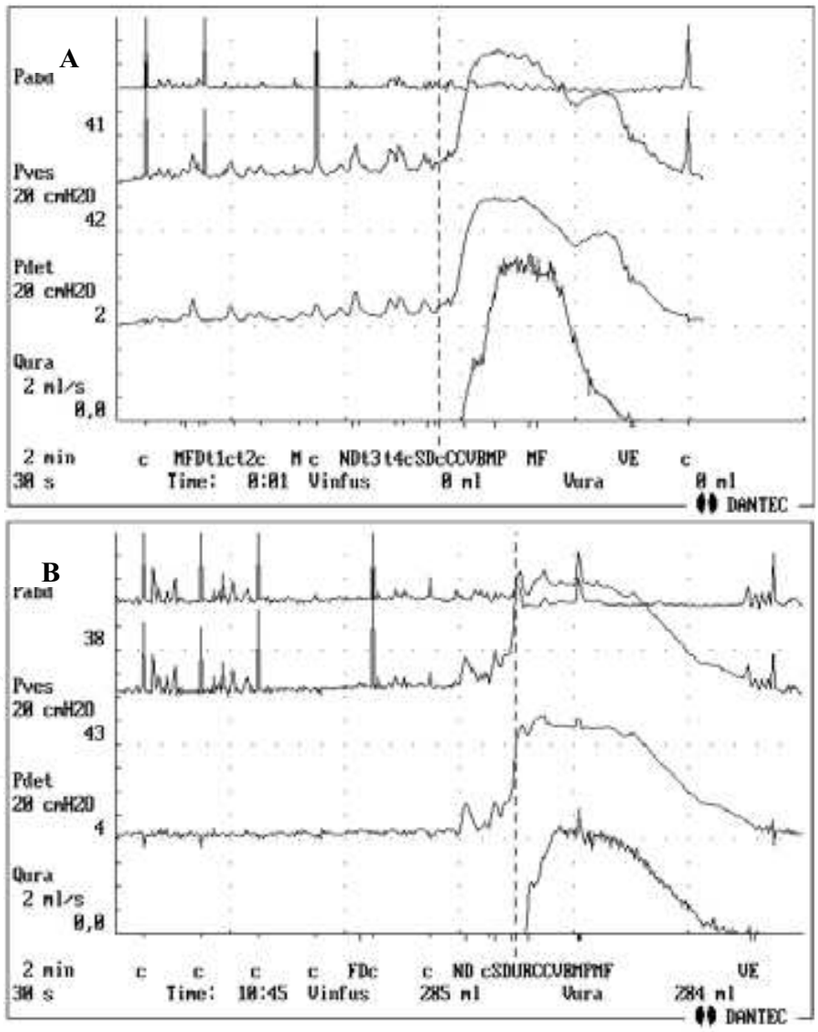


Fig. 18. Artifacts of Q_{max} on a main uroflow curve. **A**: the additional modifications in flowrate showed many small spikes on uroflow curve due to uroflowmeter. **B**: a spike artifact located at the highest plateau on a main uroflow curve due to straining

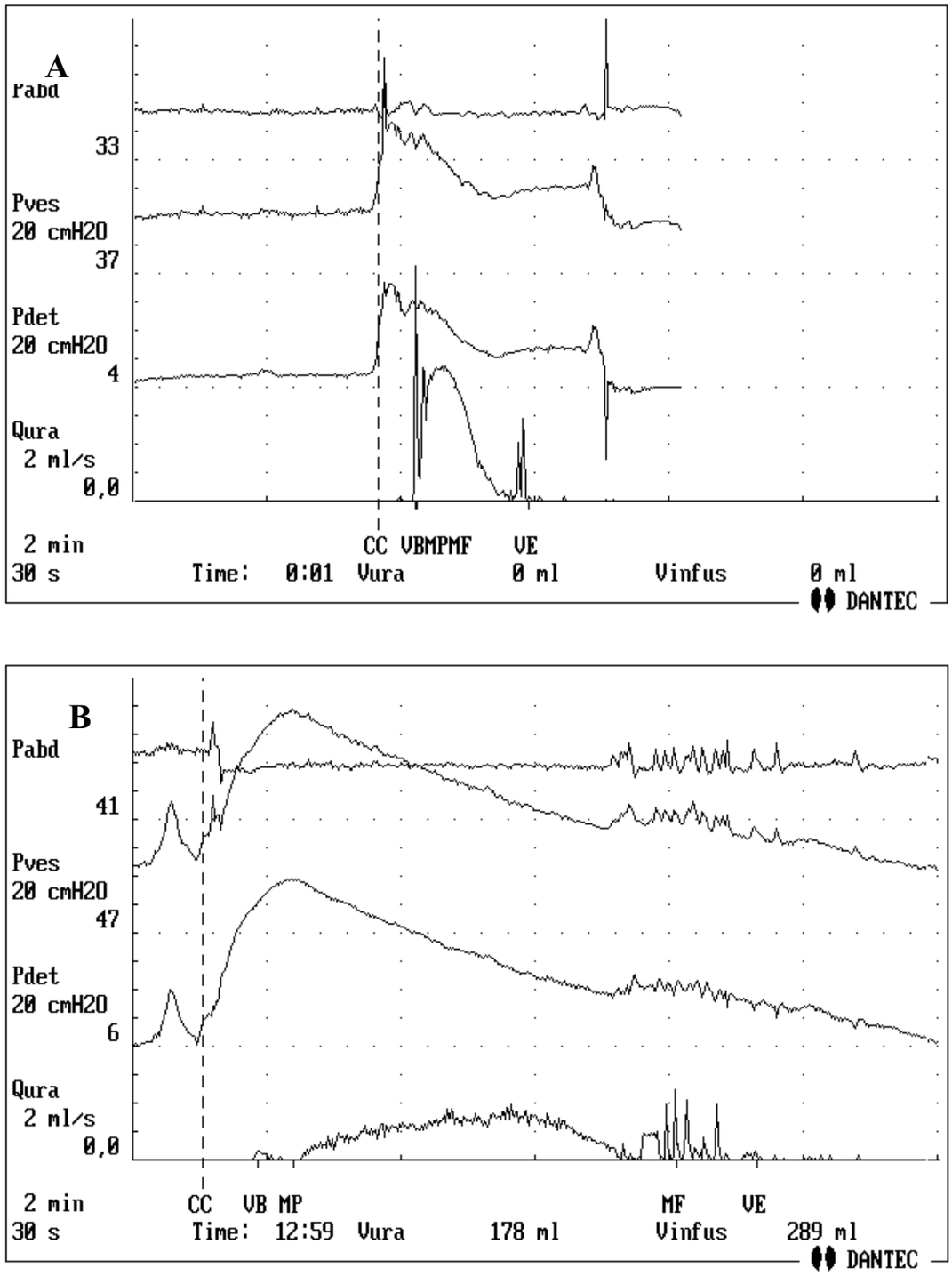
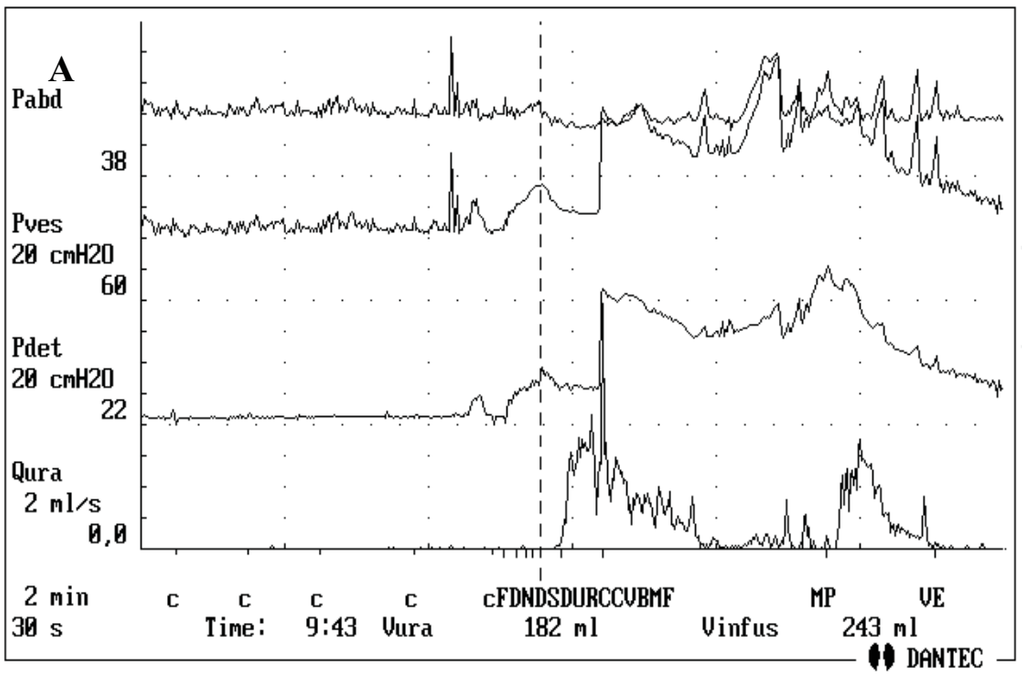
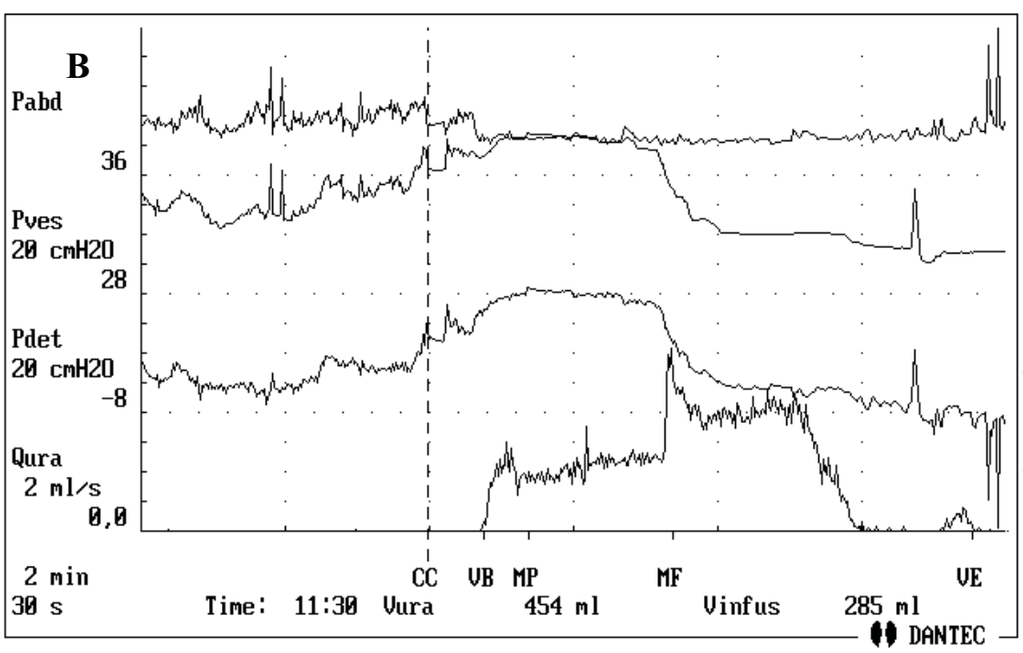


Fig. 19. Artifacts of Q_{max} at beginning and end of voiding. **A**: a spike artifact occurred at beginning of uroflow changed the location of Q_{max} in computerized data analysis. **B**: the spike artifacts appeared at end of uroflow tracing due to straining changed the location of Q_{max} in computerized data analysis


A
Pabd
38
Pves
20 cmH2O
60
Pdet
20 cmH2O
22
Qura
2 ml/s
0,0
2 min
30 s
c c c c cFDNDSDURCCVBMF MP VE
Time: 9:43 Vura 182 ml Vinfus 243 ml
DANTEC


B
Pabd
36
Pves
20 cmH2O
28
Pdet
20 cmH2O
-8
Qura
2 ml/s
0,0
2 min
30 s
CC VB MP MF VE
Time: 11:30 Vura 454 ml Vinfus 285 ml
DANTEC

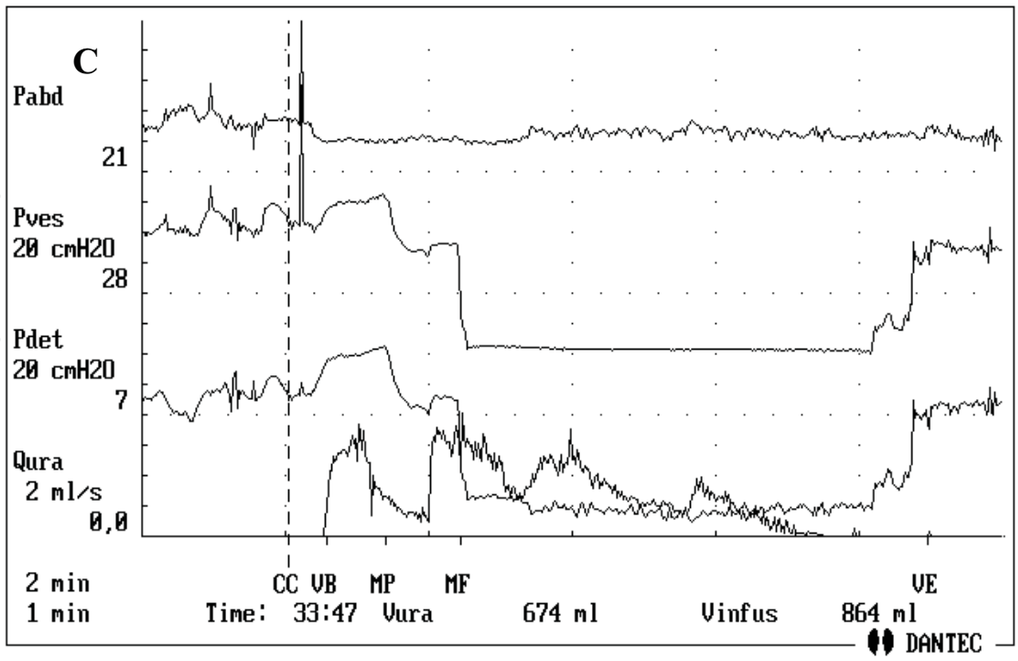


Fig. 20. The technical artifacts on pressure tracings. **A**: a periodic signal loss on P_{ves} tracing occurred at earlier stage of voiding. **B**: the signal stepwise changes on P_{ves} tracing appeared during voiding. **C**: urethral catheter was fallen out during voiding

Concerning technical artifacts during voiding, 1.4% of 582 traces showed the phasic loss of pressure signals (Fig. 20a); 3.4% had stepwise changes on P_{ves} tracing (Fig. 20b); 0.9% traces were found that urethral catheter was fallen out during voiding (Fig. 20c); and 2.2% traces were with the dislocation of rectal catheter.

With respect to the physiologic artifacts, 15.1% of 582 traces showed the spikes on P_{det} tracing due to straining (Fig. 21a); 2.1% had the dips on P_{det} tracing due to rectal contractions (Fig. 21b); 10.1% showed the spikes or dips on P_{det} tracing caused by urethral sphincter overactivity (Fig. 22a, b).

3.3.3 Effects of quality control

Comparing the manual values of pressure-flow data with computerized ones, we found the changes in parameters and urethral resistance, and in grading, classifying and diagnosing of obstruction after correction. Q_{max} had a consistently significant decrease ($p<0.001$), with a mean of 1.17 ml/ sec, and had a changed range of -0.5~10.4 ml/ sec. $P_{det.Qmax}$ had inconsistent changes with a slight systematic increase, with a mean of 0.75 cmH_2O, but no significant variation was demonstrated ($P>0.05$). Concerning the changes of $P_{det.Qmax}$ after manual correction, 321 (55.2%) of 582 traces had a significant increase ($p<0.01$), with a mean of 4.90 cmH_2O; 184 (31.6%) had a no significant decrease ($p>0.05$), with a mean of 6.16 cmH_2O; 77 (13.2%) did not change; and 505 (86.8%) underwent intra-individual changes with a range of -70 ~ 56 cmH_2O. OCO underwent a systematically significant increase by 0.067 on average ($p<0.05$); intra-individual changes were inconsistent, with a range of -1.379 ~ 0.995 (Table 9,10 fig. 23, 24, 25).

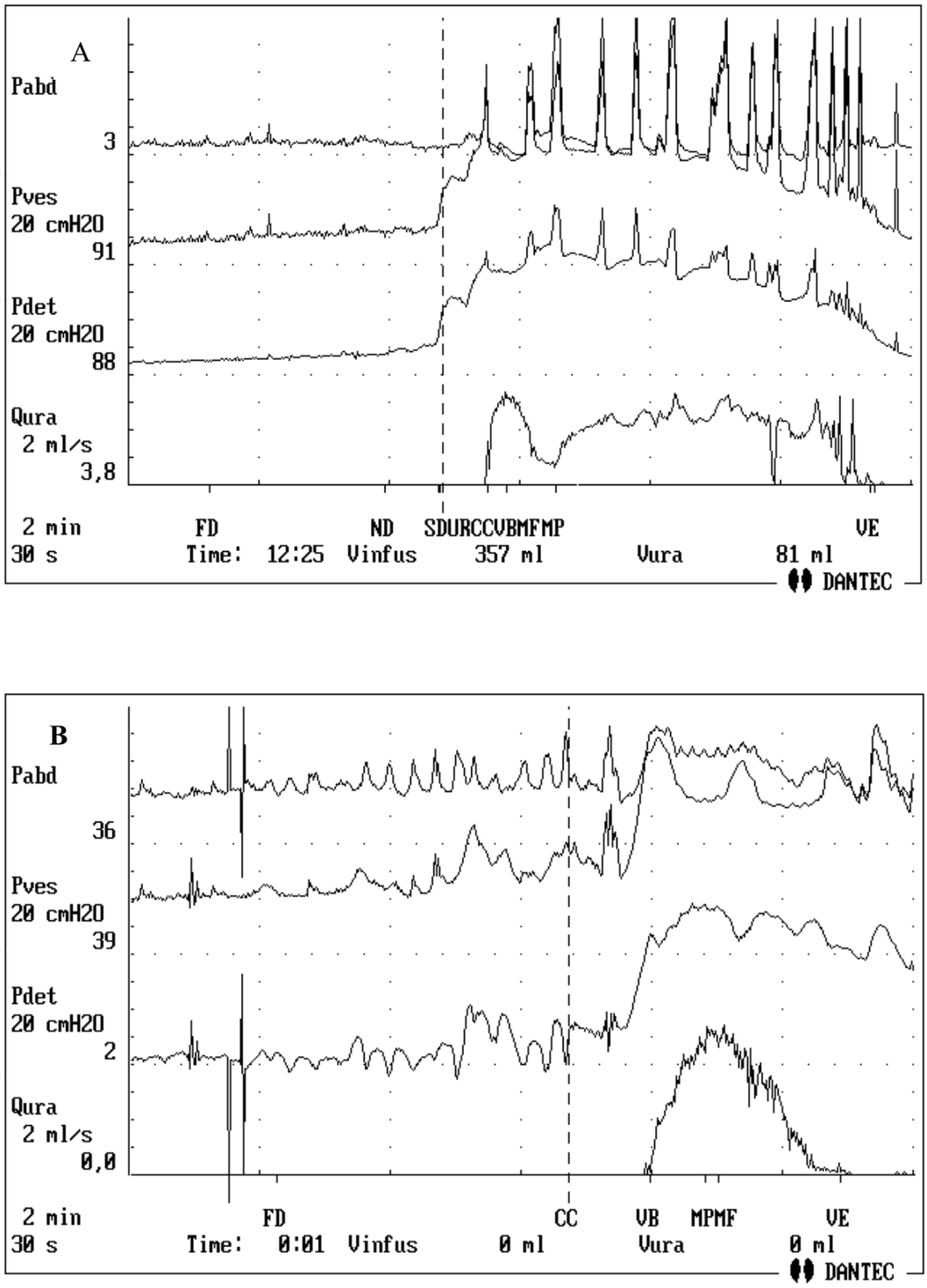


Fig. 21. The physiologic artifacts on pressure tracings. **A**: the spikes on P_{det} tracing due to a different transmission to P_{ves} and P_{abd} corresponding to straining during voiding. **B**: the dips on P_{det} tracing caused by rectal contractions

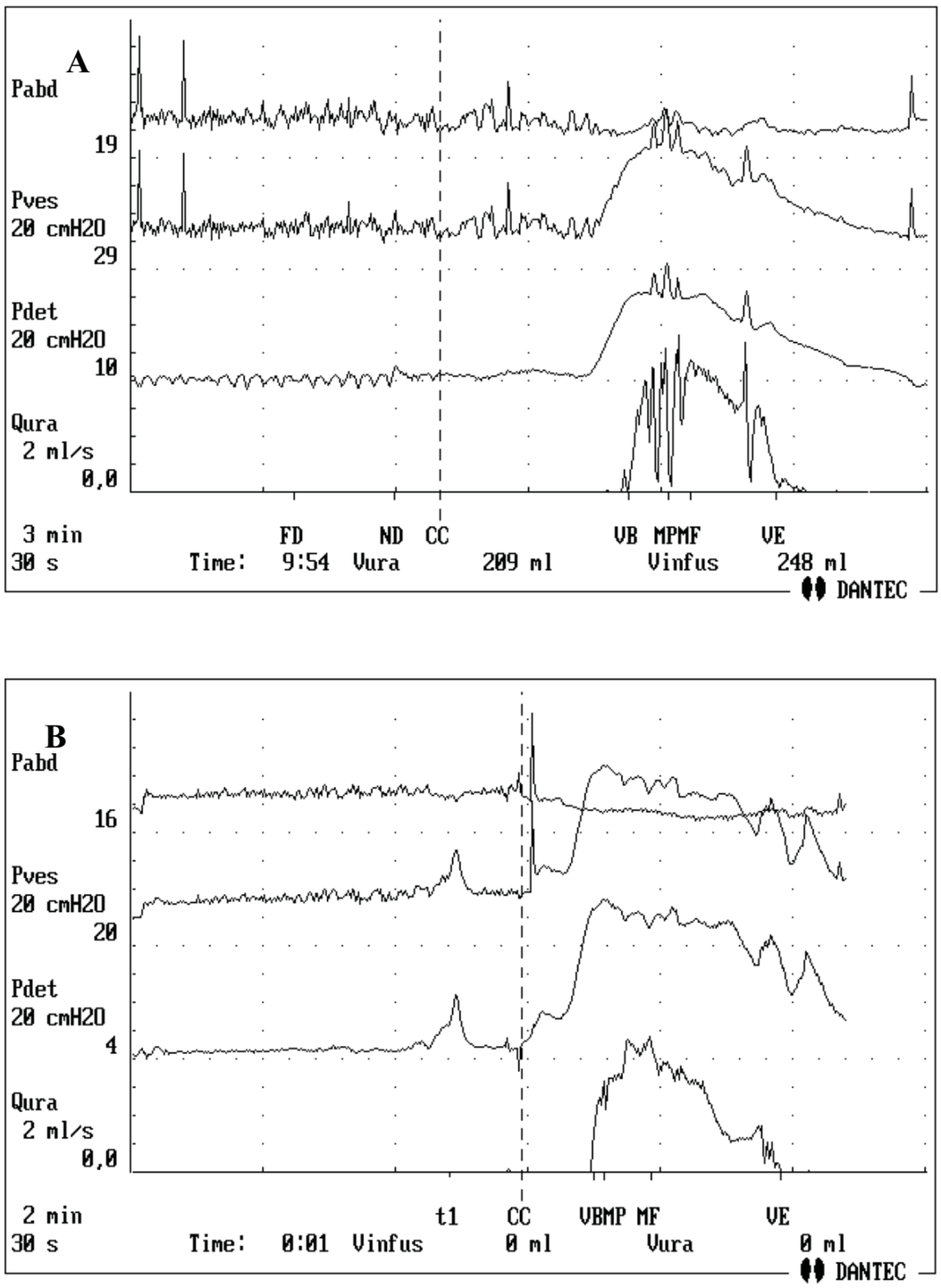


Fig. 22. The physiologic artifacts on pressure tracings due to urethral sphincter overactivity during voiding. **A**: the spikes on P_{det} tracing caused by urethral sphincter contractions during voiding. **B**: the dips on P_{det} tracing resulted from urethral sphincter relaxation during voiding

Correlation coefficients (r) of Q_{max}, $P_{det.Qmax}$ and OCO between computerized and manual readings were 0.909, 0.969 and 0.970 respectively (Table 9).

	Computerized	Manual	Change	p Value	r
Q_{max} (ml/ sec)	8.46 ± 2.87	7.29 ± 2.62	1.17 ± 1.20	<0.001	0.909
$P_{det.Qmax}$ (cmH_2O)	75.75 ± 33.34	76.50 ± 31.67	-0.75 ± 8.31	0.346	0.969
Increased $P_{det.Qmax}$ (cmH_2O)	68.93 ± 25.44	73.83 ± 25.38	-4.90 ± 6.71	0.007	0.965
Unchanged $P_{det.Qmax}$ (cmH_2O)	74.22 ± 35.32	74.22 ± 35.32	0		1
Decreased $P_{det.Qmax}$ (cmH_2O)	88.28 ± 40.48	82.13 ± 38.65	6.15 ± 7.86	0.068	0.981
OCO	1.359 ± 0.664	1.426 ± 0.652	-0.067 ± 0.162	0.040	0.970

Table 9. Changes of parameters of pressure-flow studies after manual correction (mean± SD)

	Computerized values		Manual values		Changes	
	Median	Range	Median	Range	Median	Range
Q_{max} (ml/ sec)	8.2	1.6 ~ 18.6	7	1.2 ~ 16.7	0.9	-0.5 ~ 10.4
$P_{det.Qmax}$ (cmH_2O)	69	2 ~ 264	70	20 ~ 246	-1	-70 ~ 56
Increased $P_{det.Qmax}$ (cmH_2O)	67	2 ~ 159	70	28 ~ 161	-3	-70 ~ -1
Unchanged $P_{det.Qmax}$ (cmH_2O)	62	29 ~ 246	62	29 ~ 246		
Decreased $P_{det.Qmax}$ (cmH_2O)	75	33 ~ 264	70	20 ~ 240	3	1 ~ 56
OCO	1.223	0.03 ~ 4.87	1.30	0.35 ~ 4.9	-0.06	-1.38 ~ 1.0

Table 10. Changes of parameters of pressure-flow studies after manual correction

With respect to the decreased degree of Q_{max} after correction, the percentages of decrease of ≤ 0, 0.1~0.9, 1~1.9, 2~2.9, 3~3.9 and ≥4 ml/ sec were 2.1%, 54.1%, 29.0%, 8.4%, 3.4% and 3.0% respectively (Fig. 23). Concerning the changed degree of $P_{det.Qmax}$, the percentages of increase of 1~9, 10~19 and ≥20 cmH2O were 49.3%, 3.4% and 2.4% respectively; the percentages of decrease of 1~9, 10~19 and ≥20 cmH_2O were 25.8%, 3.6% and 2.2% respectively (Fig. 24). Concerning the changed degree of OCO, the percentages of increase of 0.001~0.04, 0.05~0.14, 0.15~0.24, 0.25~0.49 and ≥0.5 were 22.5%, 44.0%, 7.7%, 5.0% and 2.2% respectively; the percentages of decrease of 0.001~0.24 and ≥0.25 were 5.5% and 13.1% respectively (Fig. 25).

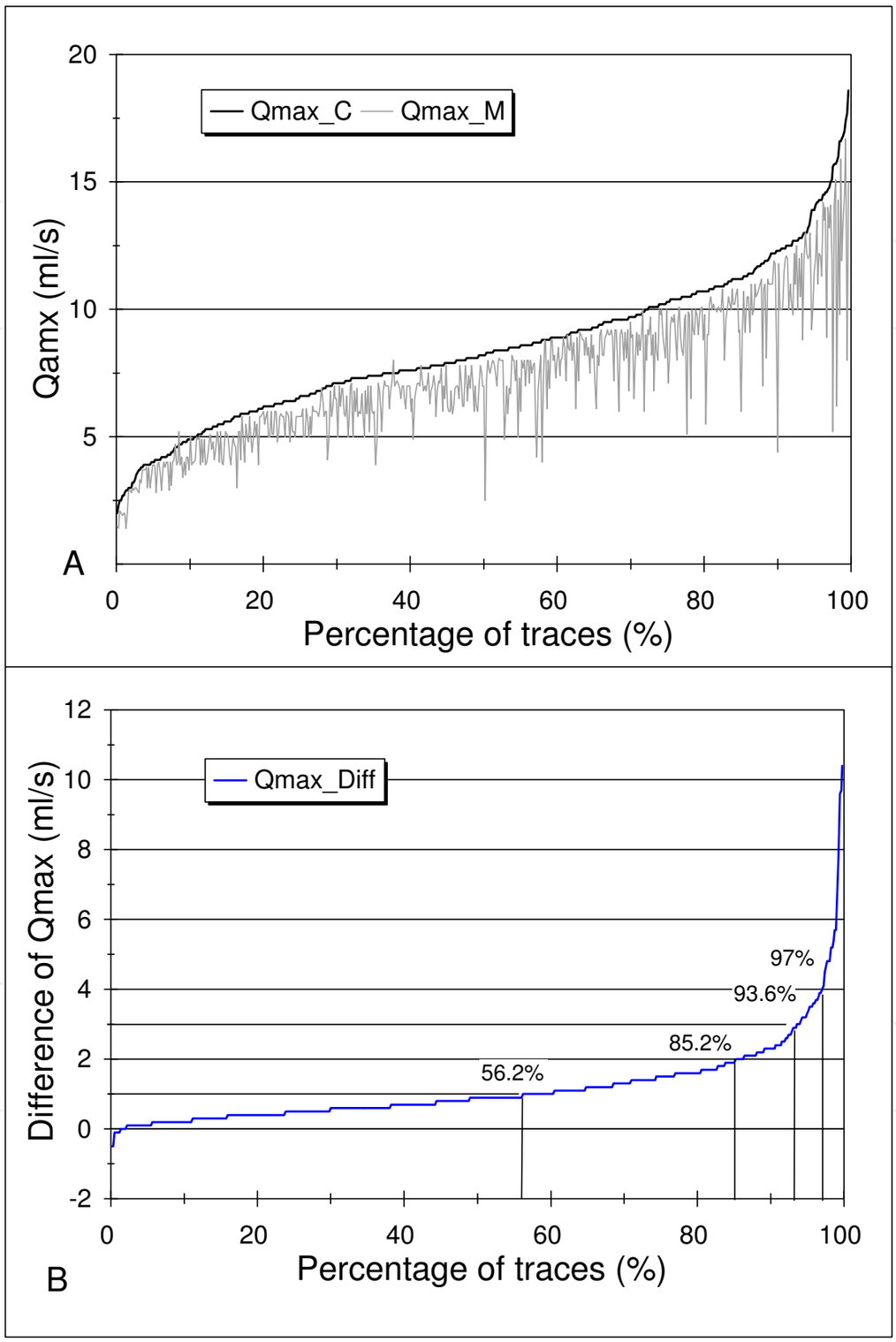


Fig. 23. **A**: Q_{max} of computerized and manual readings; **B**: the difference of Q_{max} between computerized and manual readings and the percentages of change in 582 pressure-flow traces

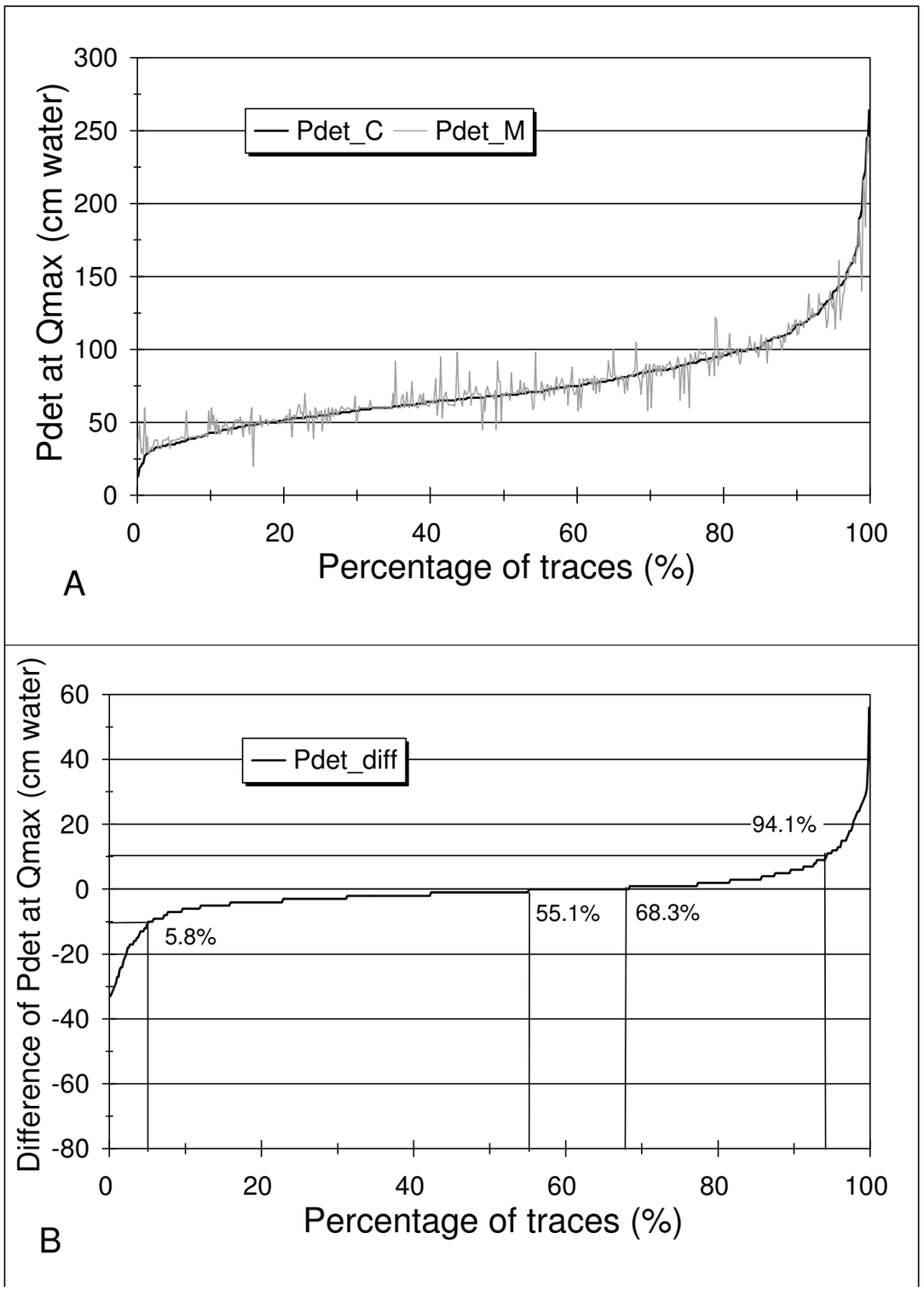


Fig. 24. **A**: $P_{det.Qmax}$ of computerized and manual readings; **B**: the difference of $P_{det.Qmax}$ between computerized and manual readings and the percentages of change in 582 pressure-flow traces

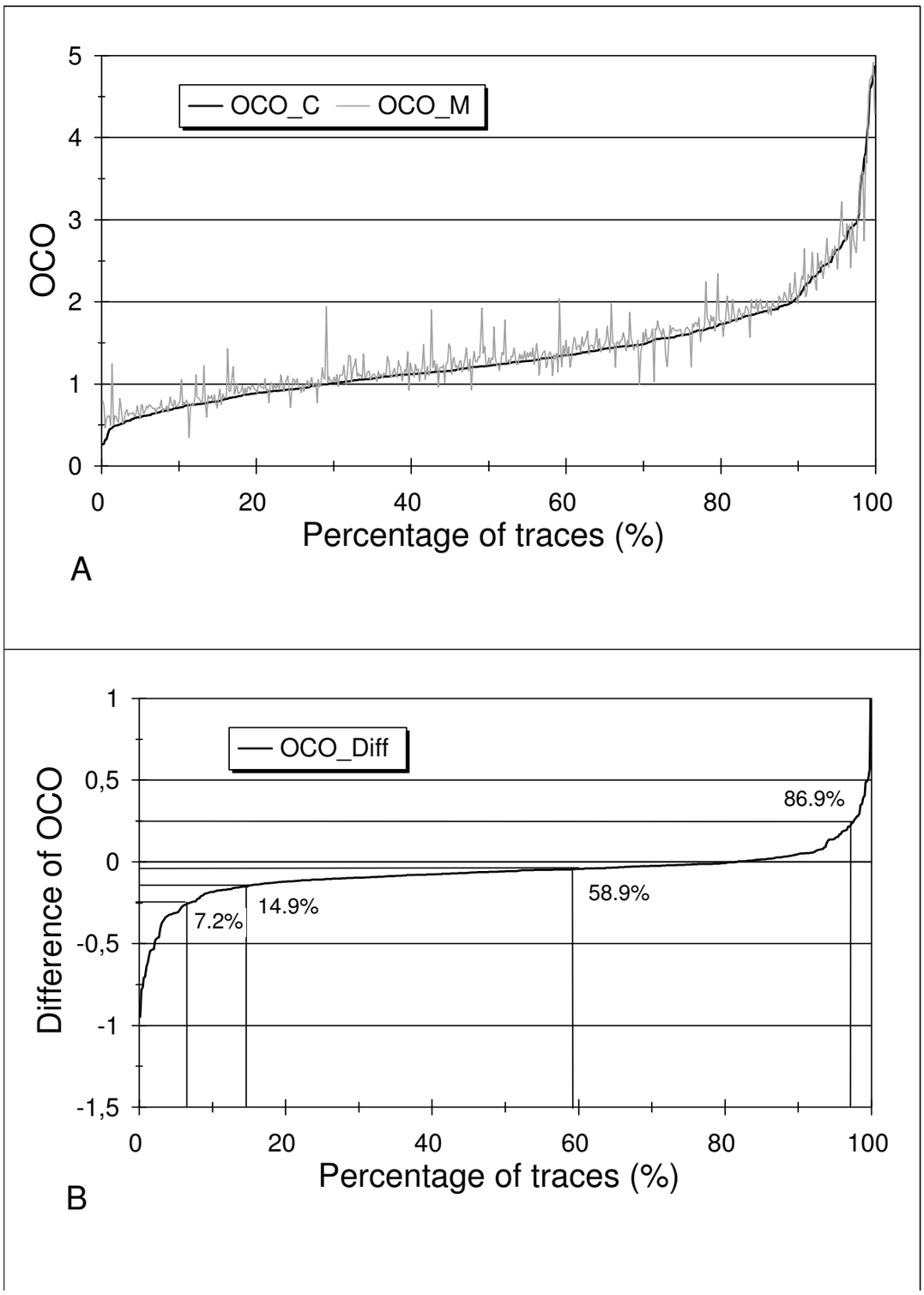


Fig. 25. **A**: OCO calculated according to computerized and manual readings; **B**: the difference of OCO between computerized and manual readings and the percentages of change in 582 pressure-flow traces

The percentages in classification using ICS nomogram and in grades using Schäfer nomogram were shown in Table 11. Comparing these percentages of manual results with computerized ones, a significant systematic difference was found. Using ICS nomogram, the obstructed percentage increased from 69.8% to 73.9% ($p<0.05$), and unobstructed one decreased from 8.8% to 5.3% ($p<0.05$). Using Schäfer nomogram, the obstructed percentage (III-VI) increased from 72.5% to 77.3% ($p<0.01$), and unobstructed one (0-I) decreased from 9.1% to 5.5% ($p<0.01$). Systematically, the distribution and degree of obstruction had a significant increase after correction. However, the intra-individual changes of classification and grade were different. After manual correction, 64 (11.0%) of 582 traces changed the classification in ICS nomogram. 53 (82.8%) of 64 traces increased obstructed degree, and 11 (17.2%) decreased one using ICS nomogram (Table 12). Using Schäfer nomogram, 168 (28.9%) of 582 traces changed the grade after correction. 143 (85.1%) of 168 traces increased obstructed degree, and 25 (14.9%) decreased one. A trace with a great change moved from 0 to IV grade, and the most of traces (94.6%) changed one grade after correction (Table 13).

	Computerized reading		Manual reading		
	No	%	No	%	p Value
ICS nomogram					< 0.05
Obstructed	406	69.8	430	73.9	
Equivocal	125	21.5	121	20.8	
Unobstructed	51	8.8	31	5.3	
Schäfer nomogram					< 0.01
0	6	1.0	1	0.2	
I	47	8.1	31	5.3	
II	107	18.4	100	17.2	
III	179	30.8	164	28.2	
IV	166	28.5	182	31.3	
V	40	6.9	64	11.0	
VI	37	6.4	40	6.9	

Table 11. Difference of percentages between computerized and manual reading in classifications of ICS nomogram and in grades of Schäfer nomogram

	No	%
Unobstructed → Equivocal	21	32.8
Equivocal → Obstructed	30	46.9
Unobstructed → Obstructed	2	3.1
Equivocal → Unobstructed	3	4.7
Obstructed → Equivocal	8	12.5
Total	64	100
Shifting into obstructed zone	32	80
Shifting out of obstructed zone	8	20
Total	40	100

Table 12. Shifts of measurements in classification of ICS nomogram after manual correction

After manual correction, 40 (6.9%) of 582 traces changed the diagnosis of obstruction using ICS nomogram; 32 (80%) of 40 traces shifted into obstructed zone, and 8 (20%) shifted out of one (Table 4, fig. 5, 6). Using Schäfer nomogram, 42 (7.2%) of 582 traces changed the diagnosis of obstruction. 35 (83.3%) of 42 traces moved from <III to ≥III grade, and 7 (16.7%) moved from ≥III to <III grade (Table 13).

	No	%
Increased 1 grade	135	80.3
Increased 2 grades	6	3.6
Increased 3 grades	1	0.6
Increased 4 grades	1	0.6
Decreased 1 grade	24	14.3
Decreased 2 grades	1	0.6
Total	168	100
< III → ≥ III grade	35	83.3
≥ III → < III grade	7	16.7
Total	42	100

Table 13. Changes of measurements in grading of Schäfer nomogram after manual correction

4. Discussion

Quality control involves in urodynamic investigation and retrospective analysis. Quality control and plausibility check during investigation are the best way to avoid and to correct artifacts at an early stage; quality control in retrospective analysis is also necessary. Quality control relies on knowledge of typical values and signal patterns recognition (Schäfer 1998). The urodynamic standards for quality control and their application in clinical urodynamic practice will be discussed from these aspects.

4.1 Quality control relies on knowledge of typical values

Quality control and plausibility check during investigation are necessary for collecting of reliable and accurate urodynamic data, which are free of the technical errors and artifacts. The typical value ranges, especially TVR for initial resting pressures, are the tool for checking the plausibility of measurement quantitatively. The correct initial resting pressures are the important factors to undergo a good cystometry; and a wrong resting pressure usually is beyond its typical value range. The proper initial resting pressures indicate two means: one is correct zero setting, another one is correct pressure reference level establishing according to the standard of ICS. The ICS has defined that all systems are zeroed at atmospheric pressure, and the pressure reference point is the level of the superior edge of the symphysis pubis (Abrams et al. 1988). However, there are still some investigators who do not obey the standard of ICS, and continue to use initial resting P_{ves} and P_{abd} as zero by balance. This is a common mistake in clinical urodynamic practice, and often leads to above-mentioned type I and type IV errors. Our study found that the relaxation of pelvic floor during voiding was a typical physiologic behavior. It appears that type I error has a normal P_{det} value. However, type Ia error has either a lower P_{abd} or a lower P_{ves} due to intra-rectal and intravesical zero setting; this lower P_{abd} often becomes negative during voiding because of over-relaxation of pelvic floor. With a negative P_{abd}, a P_{det} value higher than P_{ves} can be calculated, but this P_{det} is meaningless; this is called type IV error. Type Ib error often is caused by a wrong pressure reference level establishing. It seems that this error does not lead to any serious consequences for P_{det} is normal; but it should be corrected for the purpose of quality control and standardisation. Type I and IV errors can be avoided and solved by setting zero and establishing a pressure reference level correctly.

Type II error shows a negative initial resting Pdet caused by the atypical initial resting P_{ves} and P_{abd} values. Type IIa error has a lower P_{ves} than typical value, which often results from the problems of pressure transmission in urethral catheter and tubing, for example, air bubbles, catheter blocked and urethral catheter dislocation. It can be corrected by flushing gently through the P_{ves} transducer and tubing or adjusting the position of urethral catheter. Type IIb error has a higher P_{abd} than typical value, which often is related to an over-filling of rectal catheter balloon. Reducing the balloon filling to a proper volume and adjusting the P_{abd} to its typical range can solve this type of error.

Type III error shows a too high initial resting P_{det}. In our study, 10 cmH_2O pressure has been suggested as the upper limit of a maximum possible resting value for P_{det}. We have found that P_{det} increases 5~6 cmH_2O during filling phase according to the typical value range; then, an over 10 cmH_2O initial resting P_{det} seems to be impossible if the detrusor overactivity has been ruled out. However, this value is relatively definite. Type IIIa error has a relatively higher P_{ves} than typical range, which is often due to the problems of pressure transmission of P_{ves}, for example, urethral catheter blacked, urethral catheter dislocation. The solution is the same with that of type IIa error. Type IIIb error has a relatively lower P_{abd} than typical range, which is often related to a less filling volume of rectal catheter balloon or rectal catheter dislocation. Re-filling the balloon to a proper volume or adjusting the position of rectal catheter can correct this type of error.

From the above-mentioned analyses for the technical errors, it can be demonstrated that the suggested typical value ranges for initial resting pressures are sensitive and reliable indicator for a plausible and correct measurement. These ranges developed from our retrospective data analysis and calculation are in accord with ones recommended by

Schäfer in the ICS Standardization Report " Good Urodynamic Practice "; for example, our calculated range for initial resting P_{det} is 0~4 cmH_2O, and recommended range is 0~5 cmH_2O (Schaefer et al. 2002). It means that the initial resting detrusor pressure should be close to zero. However, our suggested TVR for P_{det} is not simply equal to a direct mathematical subtraction between two TVR of P_{ves} and P_{abd}. The reason may be that our study has been performed on the base of conventional cystometric data, and these data contain considerable cases with negative initial resting P_{det}. This leads to the difference between the ranges from statistical analysis for data and ones from the direct mathematical subtraction. However, we think the former is much more suitable to the present situation of clinical urodynamic practice. On the other hand, these suggested typical value ranges for initial resting pressures can only be used in the sitting or standing position. For supine position, the ranges for P_{ves} and P_{abd} are lower than those of standing and sitting positions; but the typical range for P_{det} is the same among all positions. Moreover, our study has found that 11.5% of traces with negative initial resting P_{det} recover the typical positive P_{det} value during initial 30 seconds of filling. This type of short-time negative initial P_{det} is often related to two causes. One is the rectal contractions during this period of time. Another one is that the contact of catheter tip with bladder wall interferes with the pressure transmission in initial filling phase. Once the tip leaves bladder mucosa with the increase of media around it, the pressure transmission will become normal. In these cases, the measurements can go on well. If a negative initial pressure continues for a longer period of time, the pressure signals will deteriorate further; and the measurement will have to be stopped to check and correct the errors. In this situation, a repeated measurement is often necessary to get a reliable result. Generally, using the typical value ranges for initial resting pressures is an effective for the plausibility check and quality control of cystometry, and is a reliable indicator of good investigation.

Our results suggest that detrusor pressure usually increases 5~6 cmH_2O during filling in 50% TVR, and TVR of detrusor compliance is 26.6~70.8 ml/ cmH_2O. Then, it is necessary to determine the dependency on the filling speed by interrupting filling for some period of time when a significant steady pressure increase beyond above-mentioned change range and TVR of compliance is observed. On the other hand, MCC recorded at end of filling should be comparable with the typical voided volume recorded in bladder diary of patient.

One of the significant parameters during voiding is P_{abd} at relaxation. In our study, TVR of this pressure value is 25~38 cmH_2O. It means that during voiding P_{abd} has a decrease with a mean of 2.7 cmH_2O due to the relaxation of pelvic floor; therefore, relaxation during voiding is a typical physiological pattern. However, it may be lead to type IV error when it combines with a wrong lower initial resting P_{abd}. At this time, a repeated measurement with correct initial resting pressures will be necessary. This study has indicated that Q_{max} and V_{void} recorded in cystometry are comparable with those of free uroflowmetry; then, they are also important values for plausibility control of voiding cystometry. It means that a free uroflowmetry with an over 150 ml V_{void} before cystometry is necessary, and Q_{max} and V_{void} from cystometry should be comparable with those of free uroflowmetry.

Although it is impossible to specify typical pressure values ranges at initial voiding, the similar typical value ranges as for the initial resting pressures may be applied for the post-void pressures. It is important to record a longer post-voiding phase until the pressure values return to the plausible resting value levels. In view of this, we have also suggested TVR for post-void resting pressures for the plausibility control of voiding phase. It is

interesting that 50% TVR for post-void P_{abd} is the same with that of filling end. It means that P_{abd} has not obvious difference before and after voiding except for during voiding. TVR for post-void P_{ves} and P_{det} are slightly higher than those of filling end, and P_{det} has an increase with a mean of 6 cmH_2O. This slight increase is acceptable, and is related to the post-void residual volume. In the elderly males with LUTS, the post-void residual volumes of different degrees are typical pathophysiological changes for this population. Therefore, the suggested TVR for post-void pressures are with the specificity of population. With the view of quality control, post-void P_{ves} and P_{det} should be close to ones at end of filling as much as possible except for the factor of high post-void residual volume. If unlike this, it suggests the problems of signal quality during voiding. Using a similar strategy to the initial resting pressures, we also can define two types of errors associated with voiding phase. Type V errors show a significant high post-void P_{ves} and P_{det} that are not relevant to a high post-void residual volume. Type Va error is caused by the signal loss ("dead" signal) of P_{ves} or the urethral catheter dislocation during voiding. If this error occurs before Q_{max} arriving, or a complete pressure-flow analysis is requested, a repeated measurement will be necessary. Type Vb error is related to the rectal catheter dislocation or the signal loss of P_{abd} tracing during voiding. Because P_{abd} is relatively unchangeable before and after voiding, it seems that this type of error can be corrected using TVR for P_{abd}. However, if the accurate Q_{max} and $P_{det.Qmax}$ are required in the precise pressure-flow analysis, the repetition will be unable to be avoided. Type VI error often results from the urethral catheter loss during voiding. For this type of error, the strategy for repetition is the same with that of type Va error. Generally, TVR of post-void pressures also are important for plausibility check and quality control during voiding cystometry. It seems to be more difficult to define an unvague upper limit for TVR of post-void Pdet because of the considerable variability. Usually, the solution for the errors and artifacts during voiding phase is repetition.

4.2 Quality control relies on signal patterns recognition

Quality control of urodynamic data relies on either static resting values in typical range, which is quantitative plausibility check for signal quality, or dynamic typical signal patterns, which is qualitative plausibility check for signal quality. To acquire the high quality urodynamic data, the investigators must conscientiously observe the signal patterns and changes at all stages of the investigation together with continuous signal testing. Therefore, keeping the above-described typical signal patterns in mind is necessary; the aim is at first to avoid artifacts and at second to identify and to correct all atypical signal patterns and artifacts immediately during investigation.

We can check the signal plausibility through examining the signal quality from four gradations of TSP during any phases of study. Before or at beginning of filling, a high quality signal must have the same fine structure between P_{ves} and P_{abd} tracings (pattern I); must show the identical minor changes in response to the patient's activity, for example, breathing, talking or moving (pattern II); and must show the equal major changes corresponding to cough tests (pattern III). P_{det} tracing dose not have any significant changes. If there are not any fine structure and minor changes on P_{ves} or P_{abd} tracings, or there are some obvious up- or down-spikes on P_{det} tracing corresponding to the test-coughs, the investigation will be unable to start or will be stopped to check the cause for poor signal quality. The common causes and the correction for them can be described as the following. The bubbles existed in catheters or tubings often lead to a problem for

pressure transmission; then, both the bladder and rectal lines should be flushed once more to ensure that all bubbles have been removed. The connection leaks may result in a low pressure signal. When the leaks are demonstrated by flushing, all connections in the lines must be examined and tighten to correct them. An urethral chatter located in the bladder neck or urethra, or a rectal catheter closed to the anal verge may also lead to the problems of signal quality. In these cases, the catheter positions must be adjusted to ensure urethral catheter in the bladder, or to position the rectal catheter around 10 cm above the anal verge. Sometimes, faecal loading may interfere with the signal of P_{abd}; therefore, the patient must be asked to remove it before investigation. A catheter blocked or a catheter with a kink can hinder the pressure signal transmission. In these cases, it is necessary to flush catheter or to renew one. Once these errors are corrected, the typical and proper signal patterns are observed, and equal changes corresponding to test-coughs between P_{ves} and P_{abd} are demonstrated, the bladder filling can start or recommence with the high quality signals. In the initial filling phase, there often are two types of major changes: straining and rectal contractions (pattern IV). Straining also is a tool for testing signal quality automatically; and the good-quality signals must have the equal responses to straining between P_{ves} and P_{abd}. The initial rectal contractions often are related to faecal loading or a big balloon filling volume. Rectal contraction may lead to a negative initial P_{det}. With rectal contractions, a measurement may go on as they can be corrected in retrospective analysis; however, the interference from rectal contractions should be ruled out in a perfect measurement. It is very important to observe and test signals, and to correct any errors before starting investigation. The high-quality initial resting signals are the premise to finish a precise and reliable cystometry.

Usually, the perfect signals at beginning of measurement stay throughout all investigation. However, it is possible that the signal quality deteriorates at any stage of cystometry, both good and bad initial signals. Therefore, the conscientious observation of signal quality and the plausibility control of signals during filling phase are crucial too. The strategy for TSP recognition and analysis during filling is the same with the initial filling phase; it is also carried out from four gradations of TSP. At any moment of filling phase, we must observe the signal patterns from four gradations: fine structure, minor changes, test-cough changes and major changes, and compare them among P_{ves}, P_{abd} and P_{det} tracings. If the deterioration of signal quality is occurred, or atypical signal patterns are observed at any stage, the investigation must be stopped and the causes of poor signal quality must be found. The investigation can continue after errors have been corrected. For the high-quality signals during filling, P_{ves} and P_{abd} must have the same fine structure (pattern I); must show the identical minor changes in response to the patient's activity, for example, breathing, talking or moving (pattern II); and must have the equal major changes corresponding to test-coughs (pattern III). There are no fine structure and minor changes on P_{det} tracing; at most, there may be some small biphasic spikes corresponding to test-coughs on it. If fine structure and minor changes on P_{ves} or P_{abd} tracings disappear, or the obvious up- or down-spikes appear on P_{det} tracing corresponding to the test-coughs at regular intervals, these points suggest an indicator of signal quality deterioration. In these situations, the investigation has to be stopped to investigate the causes for poor signal quality. Usually, the causes can be found as the following. Firstly, the bubbles existed in catheters or tubings do not be flushed completely, or appear again because of a loose connection. Secondly, the connection leaks do not be corrected completely. Thirdly, the urethral catheter moves into the bladder neck

or urethral, or rectal catheter moves into the anal verge. Fourthly, faecal loading influences the signal of P_{abd}. For the correction of these errors, the methods are the same with those of initial filling phase. Finally, the contact of catheter tip with bladder wall often interferes with the pressure signal transmission; flushing through urethral catheter can correct this error. Usually, there are three types of typical major changes during filling: straining, detrusor overactivity and rectal contractions (pattern IV). Like the test-coughs, straining can test signals automatically; the good-quality signals show the equal changes on P_{ves} and P_{abd} tracings corresponding to straining, and no changes occur on P_{det} tracing. Unlike this, the causes of poor signal transmission must be checked. Detrusor overactivity is a typical major signal pattern during filling, which appears in the forms of single or multiple unstable detrusor contractions in 33.7% traces analyzed. We must familiarize ourselves with this typical pattern in order to discriminate from the atypical patterns. The changes on P_{ves} and P_{abd} tracings are identical when the unstable detrusor contractions occur. However, the technical factors resulting in detrusor overactivity, for example, fast filling or too cold media for filling, must be checked and removed. Rectal activity is another typical major signal pattern during filling, which is characterized by single or multiple rectal contractions. Its incidence is 17.4% in the traces analyzed. We must also recognize this typical pattern. There is a positive wave on P_{abd} tracing and a negative wave on P_{det} tracing when a rectal contraction happens. Faecal loading and a big balloon filling volume often lead to the rectal contractions. With rectal contractions, the measurement may continue because they can be recognized and corrected in retrospective analysis as artifacts. However, if the rectal contractions interfere with the data analysis, especially with the analysis for detrusor overactivity, a repeated measurement will usually be necessary. During filling, the cough tests at regular intervals, for example every minute, are the powerful tool for checking the plausibility of signals.

Usually, the plausibility control of signals during voiding is difficult; therefore, it is very important to ensure the high-quality signals to go into voiding phase. For this purpose, the cough tests before voiding are the effective tool for ensuring the good signal quality. If there are the obvious different changes between P_{ves} and P_{abd} tracings corresponding to the test-coughs before voiding, this will be an indicator of signal deterioration, and these signals can not be allowed into voiding (Fig. 14b). In this situation, the investigation must be interrupted to examine for the causes of poor signal quality, and to rule them out. The pre-voiding phase may be recorded for a period as long as possible in order to get sufficient information for a signal control and to have enough time to test signals by coughs.

As voiding phase goes on quickly, and more complex anatomical and physiological aspects are involved in this process, quality control during voiding is difficult. Comparing with before and during filling phases, we can do fewer things for signal quality control and plausibility check. However, we must still keep conscientious observation of signals and TSP recognition for there are various artifacts occurred during voiding. Firstly, there are the same fine structure (Pattern I) and minor changes (pattern II) on P_{ves} and P_{abd} tracings, which suggest that the signals are "live". When fine structure and minor changes on P_{ves} or P_{abd} tracing disappear during voiding, the tracing often shows the stepwise changes with a "dead" line or a sudden drop (Fig. 14b, 14c, Fig. 16). One of the common causes is the catheter dislocation or loss. Urethral catheter often moves into the bladder neck or the sphincter area, or is projected with the urine stream during voiding. Similarly, rectal catheter often slips down into the anal sphincter area, or falls out. If these errors appear

before maximum uroflow rate (Q_{max}) or a complete voiding is request for the purpose of pressure-flow analysis, the measurement should be repeated. Secondly, typical major signal patterns (Pattern IV) must be recognized. During voiding, typical pattern of detrusor contraction is easy to identify (Fig. 11a); however, identification usually is difficult when some special patterns appear. After-contraction is a common finding and a normal phenomenon (Fig. 11b). Fluctuation contraction often associates with detrusor underactivity, which suggests that detrusor is unable to empty the bladder depending on once a contraction (Fig. 11c). This type of fluctuation contraction must be distinguished from that of detrusor-sphincter dyssynergia. The former shows the simultaneous changes among P_{ves}, P_{det} and uroflow tracings, but the latter has the rapid increases of P_{ves} and P_{det} between two urine spurts. Usually, a unstable detrusor may get to a high pressure level before voiding due to involuntary contraction, the pressure drops suddenly as soon as uroflow starts (Fig. 11b). This unstable detrusor voiding often leads to an illusion. Straining is one of the most common typical patterns during voiding, which is found in 71% traces analyzed. With the good signal quality and the equal signal transmission, there will not be any artifacts on P_{det} tracing. When the signal transmissions between P_{ves} and P_{det} tracings are unequal, there will be some spike artifacts on P_{det} tracing (Fig. 15b), which must be corrected in retrospective analysis. Rectal contraction also is a type of TSP during voiding, which occurs in 2.1% traces analyzed. Rectal contractions may lead to the dip artifacts on P_{det} tracing, which can be corrected in retrospective analysis. Relaxation of pelvic floor during voiding is another type of TSP, which appears in 15.3% traces analyzed. Relaxation indicates the significance of the high-quality recording of P_{abd}, which can eliminate the impact of perivesical pressures on P_{ves}. During voiding, P_{ves} and P_{det} tracings increase and decrease with detrusor contraction smooth and steady. If they drop suddenly, the common cause is the catheter's dislocation or loss.

The plausibility check for signals and signal tests after voiding are necessary for demonstrating the signal quality during voiding, and for ensuring the high-quality pressure-flow data. A longer post-voiding recording phase can provide us with sufficient information for quality control and enough time to test signals. In this phase, cough tests are the powerful tool to check the signal quality during voiding. After voiding, there still are the identical fine structure and minor change on P_{ves} and P_{abd} tracings, and the tracings show the equal changes corresponding to test-coughs; these points suggest the high-quality signals during voiding. If not, the causes of poor signal quality must be checked. The common causes also are the catheter's dislocation or loss, and signal loss on P_{ves} or P_{abd} tracing (Fig. 13b, Fig. 14b, 14c and Fig.16). If these errors appear before Q_{max} or a complete voiding is request for a precise pressure-flow analysis, the investigation must be repeated.

Finally, pattern recognition is based on the scales of signals. A changed scale often leads an illusion; therefore, the scales should be kept unchanged as much as possible either during investigation or in retrospective analysis (Fig. 17).

4.3 Quality control in retrospective analysis

The best way of quality control is to avoid artifacts and technical errors and to eliminate them at an early stage during investigation; the retrospective correction is the worst solution. However, retrospective correction is unable to be lacked for the artifacts existed, especially in computerized data. In our retrospective analysis, artifacts during filling were mainly related to the wrong initial resting pressures, spikes due to test-coughs and periodic

signal loss or stepwise changes. The correction for these artifacts is easy comparing with those of voiding cystometry. Therefore, we mainly discussed the recognition and correction for artifacts during pressure-flow investigation, demonstrated the effects of correction, and indicated the role and significance of retrospective quality control.

Pressure-flow studies can provide us with a diagnostic standard for bladder outlet obstruction, and measure the urethral resistance and changes. In pressure-flow analysis, the obstructed degree and urethral resistance usually depend on two variables: Q_{max} and $P_{det.Qmax}$. The problem that we face is how to obtain the reliable values of Q_{max} and $P_{det.Qmax}$, which are free of various artifacts, and to ensure the clinical diagnosis and research an objective and reliable result. Therefore, quality control of pressure-flow data becomes increasingly important; it can be performed either during collection of data or in retrospective analysis of data. Quality control during collection of data can avoid, reduce or eliminate artifacts. On the other hand, the artifacts existed in data can only be corrected in retrospective analysis. This is the worst solution, but is necessary for computer results. Modern computerized urodynamic systems have presented new problems in analysis of data. Almost all machines are unable to pick up and correct artifacts. Many clinicians do not examine the traces for artifacts and accept the computer's values of parameters; this must influence the clinical diagnosis and the research result significantly. The main tasks of retrospective quality control of pressure-flow data are the typical pattern identification, artifacts recognition and correction as well as manually reading for Q_{max} and $P_{det.Qmax}$ coming from computer printouts.

In the present study, 4% traces had to be discarded because of the non-interpretable and non-correctional artifacts and the pattern with multi strong strains during voiding. In the interpretable pressure-flow traces, Q_{max}, urethral resistance (OCO), grading and classifying of obstruction underwent significant systematic changes; $P_{det.Qmax}$ had no systematically significant changes, but with considerable intra-individual changes after manual correction. Q_{max} reduced consistently by 1.17 ml/ sec on average, which was similar to the result (by 1.5 ml/ sec on average) reported by Grino et al in 1645 uroflow measurements and the result (by 0.8 ml/ sec on average) reported by Madsen et al in pressure-flow studies of 25 patients (Grino et al. 1993; Madsen et al. 1995). In this study, 81.8% traces showed obvious artifacts of Q_{max}. The decreased value of Q_{max} resulted from the correction of spike artifacts and extracorporeal modifications in flowrate. 23.1% of artifacts changed the location of Q_{max} (Fig.19a and 19b). The decreased degree of Q_{max} was variable, but 83.1% readings were with 0.1~1.9 ml/ sec decrease of Q_{max}. There were 7 (1.2%) traces with increased values of Q_{max} after correction, the reason would be that the investigators changed computer results of Q_{max}. Smoothed and corrected value of Q_{max} underwent a significant decrease; still, there was a good correlation between computerized and manual values of Q_{max}. It means that manual correction has not changed the nature of Q_{max} data, the smoothed and corrected Q_{max} can reflect the condition of urethral resistance much more really. How are artifacts of Q_{max} identified? A normal uroflow curve is smooth without any rapid changes or spikes. Rapid changes in flowrate may have physiological and physical causes (Schaefer et al. 2002). The physiological spikes can result from changes in outflow resistance, for instance, sphincter and pelvic floor contraction or relaxation, or from changes in driving energy, for instance, abdominal straining. These intracorporeal physiological artifacts should be minimized during the investigation (Fig.18b, Fig.19). Extracorporeal additional modifications in the flowrate signal, which usually is small spikes, can be introduced by any funnel or collecting device of uroflowmeter (Fig.18). This type of non-physiological artifacts should be eliminated. As a simple rule of thumb, any rapid change in uroflow rate lasting

less than two seconds should be smoothed and corrected as artifacts in retrospective analysis. In a recent standardization report, ICS recommended that an internal electronic smoothing with a sliding average over two seconds was used to make electronically reading value of Q_{max} more reliable, comparable and clinically useful. In manual graphical readings of Q_{max}, a graphical line smoothing to a continuous curvature for at least a period of two seconds was drawn to get a smoothed Q_{max} value. Generally, only smoothed Q_{max} that is lower than electronically reading Q_{max} is clinically meaningful. ICS agreed that as a standard only smoothed Q_{max} values were reported (Schaefer et al. 2002).

$P_{det.Qmax}$ showed a slight systematic increase by 0.75 cmH_2O on average after manual correction, but no significant variation was demonstrated. Similarly, Madsen et al reported a no significant slight decrease of $P_{det.Qmax}$, with a mean of 2.8 cmH_2O after correction (Madsen et al. 1995). The reason would be that the location of $P_{det.Qmax}$ responds to Q_{max}; therefore, intra-individual changes of $P_{det.Qmax}$ were inconsistent. 55.2% traces had a significant increase by 4.90 cmH_2O on average, and 31.6% traces had no significant decrease by 6.15 cmH_2O on average. Although there was no systematically significant change, $P_{det.Qmax}$ indeed underwent a intra-individual considerable change ranged from -70 to 56 cmH_2O after manual correction. The artifacts of $P_{det.Qmax}$ are various and complex, and sometimes are difficult to interpret. As a smooth muscle, detrusor contracts smoothly and steadily, and then any pressure change caused by detrusor contraction must show a smooth and steady pattern without rapid changes. A typical pattern of trace of detrusor pressure during voiding is that the pressure tracings rise and drop smoothly and steadily. Therefore, any rapid changes on the curve in short time should be considered as artifacts, and must be interpreted and corrected. Artifacts of detrusor pressure during voiding have a number of types, and can be produced in a variety of ways. We may classify them into technical and physiologic artifacts. The technical artifacts may be caused by phasic signal loss, signal stepwise change and urethral catheter loss and rectal catheter dislocations; the incidences in our study are 1.4%, 3.4%, 0.9% and 2.2% respectively (Fig. 20). The physiologic artifacts are mainly the spikes and dips on P_{det} tracing resulted from the different causes. The first cause is the spikes due to straining under the condition of a difference in pressure transmission to the P_{ves} and P_{abd} (Fig. 21a); the incidence of this type of artifact is 15.1% in our study. The second one is the dips caused by rectal contractions (Fig. 21b); the incidence of this type of artifact is 2.1%. The last one is the spikes or the dips due to urethral sphincter overactivity during voiding, which is sphincter contraction (Fig 22a) or relaxation (Fig 22b); the incidence of this type of artifact is 10.1%. In retrospective quality control, the spike and dip artifacts can manually be corrected by smoothing. However, it usually is difficult to correct the technical artifacts in retrospective analysis. If they occur after Q_{max}, we may acquire two key parameters of pressure-flow study: Q_{max} and $P_{det.Qmax}$. If they appear before Q_{max} or a complete pressure-flow plot is requested for the purpose of precise analysis, the traces with these artifacts will have to be discarded.

As a continuous quantitative parameter, OCO can precisely measure the urethral resistance and change. In this study, a systematically significant increase of OCO by 0.067 on average was shown after manual correction. Intra-individually, OCO changes were inconsistent, with a range from -1.379 to 0.995. The reason would be that the inconsistent changes of P_{det} could influence those of OCO. The changes of OCO indicated that manually reading lead to higher urethral resistance, and artifacts reduced urethral resistance. Therefore, we could say that OCO calculated by manually reading values could really indicate the condition of urethral resistance.

More serious is that various artifacts have influenced the diagnosis of obstruction and the assessment of obstructed degree. Generally, it seems that artifacts lead to a less obstructed degree. In our study, ICS and Schäfer nomograms were employed to evaluate this impact. After manual correction, more traces located in obstructed zone or grades. 11.0% traces changed the classification in ICS nomogram, and 28.9% did the grade in Schäfer nomogram. Using these two nomograms, 6.9% and 7.2% traces changed the diagnosis of obstruction; 5.5% and 6.0% traces shifted into obstructed zone or grades. It could be said that computerized results produced 5.5% or 6.0% false negative diagnoses of obstruction due to various artifacts in these 582 measurements. On the other hand, 1.2% and 1.4% traces shifted out of obstructed zone or grades. It could also be said that computerized readings produced 1.2% or 1.4% false positive diagnoses of obstruction. Therefore, we could say that retrospective quality control corrected considerable false diagnoses of obstruction.

From above analyses, It was found that a corrected Q_{max} should be determined at first in retrospective analyzing of pressure-flow data; then a location of P_{det} corresponding to Q_{max} can be found, and the urethral resistance parameters, such as OCO, can be calculated. It seems that a systematically significant difference of Q_{max} results in those of OCO, classifying and grading of obstruction after manual correction.

Summarily, quality control is involved in both on-line and off-line urodynamic investigation. Getting the most out of urodynamics depends not only on a good urodynamic practice, but also on the training and experience of the clinician charged with interpreting the result (Abrams 1998). In the interpretation of pressure-flow data, the clinician must meticulously examine the trace for artifacts before accepting the computer results. At present, retrospective quality control of computerized pressure-flow data is necessary; it can get rid of the impact of artifacts on Q_{max}, P_{det}, urethral resistance, classifying and grading of obstruction, and diagnosis of obstruction. The data through quality control become more objective, reliable and acceptable, and can be used for further analysis. These effects of retrospective quality control have been demonstrated in the present study.

5. Conclusions

Quality control and plausibility check during investigation are the best way to avoid and to correct artifacts at an early stage; quality control relies on knowledge of typical values and signal patterns recognition.

Typical value ranges for pressures and other parameters in cystometry are effective tools for quantitative plausibility check and quality control of data. Typical value ranges for initial resting P_{ves} and P_{abd} are 31~42 cmH_2O and 28~39 cmH_2O in standing or sitting position respectively; and that of P_{det} is 0~4 cmH_2O, which is very close to zero. The suggested typical value ranges for the initial resting pressures are sensitive and reliable indicator for plausible and correct measurement. The errors related to initial resting pressures must be recognized and corrected before or at beginning of filling. The typical ranges for other parameters during filling and voiding phases are useful for checking plausibility of measurement. Q_{max} and V_{void} in cystometry must be comparable with those of free uroflowmetry. Typical value ranges for post-void P_{ves}, P_{abd} and P_{det} are 40~55 cmH_2O, 30~41 cmH_2O and 10~14 cmH_2O respectively. After voiding, P_{abd} has little change, P_{ves} and P_{det} are close to the levels before voiding. The suggested typical value ranges for post-void pressures are also important for the plausibility control of voiding phase.

Typical signal patterns are powerful tool for the qualitative plausibility check and quality control. Combining with typical value ranges, they allow a definitive judgment of the quality of an urodynamic investigation. We have described the TSP from four gradations: fine structure (pattern I), minor changes (pattern II), major changes corresponding to test-coughs (pattern III) and major changes (Pattern IV). At any stages of investigation, there must be the same fine structure and minor changes due to patient's breathing, talking and moving on P_{ves} and P_{abd} tracings but not on P_{det} tracing. These two patterns suggest that the signals are "live". The cough tests before or at beginning of filling, during filling at regular intervals, and before and after voiding are effective tool for checking the signal quality and plausibility. P_{ves} and P_{abd} tracings must show the equal changes corresponding to the test-coughs. Straining, detrusor overactivity and rectal contractions are typical major changes during filling; and detrusor contraction with different patterns, straining, rectal contractions and relaxation of pelvic floor during voiding are typical major changes during voiding. These major patterns have their characters, and we must be able to recognize them. Analyzing signal quality from these four gradations, we can find some atypical patterns, technical errors and artifacts and can correct them immediately in order to acquire the urodynamic data with a high-quality during investigation.

In retrospective quality control, various considerable artifacts were found in the cystometric data. The systematically significant differences of Q_{max}, urethral resistance, and classifying and grading of obstruction between manual and computerized readings suggested the existing of artifacts and their interference with the clinical judgment. The manually corrected Q_{max} had a consistently lower value; a higher value of OCO was calculated, and a more obstructed degree was assessed according to the manual readings. Although no systematically significant change of $P_{det.Qmax}$ was demonstrated after manual correction, it indeed underwent intra-individual considerable changes. Manually reading corrected considerable false diagnoses of obstruction. The effects of manual correction were shown. Therefore, retrospective quality control of computerized urodynamic data is significant and necessary; only the data throughout quality control can be used and reported.

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