ICON
INDIAN CONTINENCE FOUNDATION

ICON
Vol.1 No.2 October 1999

EDITORIAL

The response to the first issue of ICON has been encouraging. We thank all those who contacted the editorial team and shared their impressions . We are now aware of the expectations from us, and the responsibility placed on us to ensure the quality of this publication.

The issue of Incontinence and its management is slowly gaining in importance, thanks to the large body of medical literature in this regard. Medical professionals too are paying greater attention to this subject . Relentless efforts of Continence groups in the developed countries have highlighted the magnitude of Incontinence as a public health issue. Such efforts have also resulted in the formation of self-help groups, which have ameliorated the isolation, and neglect that was the incontinent patients lot.

In this issue, we bring you an article outlining the approach to the management of incontinence in myelodysplastic children. For long, such children have been suffering due to collective ignorance and neglect. The wide prevalence of myelodysplasia makes this article topical and relevant. This issue also carries the concluding part of the article on outcome measures in clinical BPH and the second part of the draft ICS guidelines on Good Urodynamic Practice.

The Indian Continence Foundation is conducting a course for nurses and care-providers in November. The announcement appears in this issue. The foundation will soon initiate a community-based prevalence survey on Incontinence and Enuresis. Readers letters on matters covered in the publication, and issues raised are most welcome.

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Manipal

"OUTCOME MEASURES IN TREATMENT OF UNCOMPLICATED BENIGN PROSTATIC OBSTRUCTION

(The first part of this article appeared in the previous issue of ICON and dealt with various scoring systems for symptoms. In this concluding part, the significance and relevance of certain objective measures are discussed - Editors)

Direct anatomical and physiological measures:

Prostate size and anatomy

Estimation of prostatic size and anatomy is performed to establish the diagnosis of BPE. If treatment is directed against changing prostatic size and / or anatomy, prostate size is used as a parameter for assessing response. Prostate size correlates poorly or not at all to symptomatology, B.O.O and treatment outcome

Digital rectal examination (DRE).

Although DRE may give a rough estimate of prostate size, its reliability is poor.

Transrectal Ultrasound Scanning (TRUS).

Planimetric volumetry is often regarded as the gold standard for prostate volume determination. Excellent correlation between the planimetric volume and the absolute volume has been demonstrated in cadavers. Reliability is very good. Different methods and formulae to measure and calculate prostate volume from different axes of the prostate are less accurate. Often, simple formulae are used to calculate prostate volume from axial, sagittal and coronal diameters. The accuracy of these seems sufficient for daily clinical use. Transition zone volume and transition zone index may be a valuable supplement to whole gland volume determination. If treatment intends to change prostate volume, measurements should be done before and after treatment.

Magnetic Resonance Imaging (MRI)

Determination of prostate volume by MRI is highly accurate and reproducible. As for TRUS, the method of calculation is important. An approximately 30% larger volume by MRI than by TRUS using 3-dimensional methods for volume determination was found.

Normal values

Prostate volume seems to change with age. As a significant overlap exists among prostate volume in LUTS and BOO, it is at present difficult to estimate appropriate "normal values" for different populations and age groups.

Morphology

It has been reported that the antero-posterior diameter increases more than the transverse diameter with age and the shape of prostate becomes round by transverse section. Changes in microscopic features of glandular, muscle and connective tissue content in the gland might be relevant.

Infravesical obstruction

"Clinical BPH" has traditionally been synonymous with "obstructive BPH". The only method to accurately assess BOO is pressure-flow studies with simultaneous recording of intra-abdominal pressure, intravesical pressure and urinary flow rate. As this is an invasive, time consuming procedure, it will probably never be adopted as a routine procedure in all patients. It is however the cornerstone in the assessment of outcome after treatments claiming to relieve B.O.O. Results should be presented as stated in the ICS standardisation report on pressure-flow studies of voiding, urethral resistance and urethral obstruction.

Indirect anatomical and physiological measures.

Cystourethroscopy

Prostatic intraurethral protrusion and bladder trabeculation are poor indicators of infravesical obstruction. Therefore, cystourethroscopy is useless as a direct indicator of outcome after treatment. In certain modalities of treatment, it may give a clue as to why a treatment has failed (e.g. stent position, presence of median lobe etc.)

Residual urine volume

Wide intra-individual variation of residual urine volume has been demonstrated by catheter or ultrasound measurement in candidates for TUR-P. In one study, the individual variation was 42% with a confidence interval of 55-228 ml. As poor bladder emptying may be due to either outlet obstruction, detrusor failure or both, correlation with outlet obstruction alone is poor. However, post treatment reduction of residual urine volume indicates improvement of outlet conditions and is likely to be more significant in assessing treatment response.

Urinary flow rate

The urinary flow rate reflects both detrusor function and outlet conditions. Urinary flow rate increases with increasing bladder volume until a certain limit and thereafter decreases. This underlines the high dependence of urinary flow rates on detrusor muscle function and explains why urinary flow rate alone is of limited help in the diagnosis of outlet obstruction. Test-retest measurements of maximum urinary flow rates have a standard deviation of about 3.5 ml/s with a wide range. A significant overlap exists between symptomatic and asymptotic men as well as between obstructive and non-obstructive voiding. Correction for voided volume does not change this finding.

Change in flow rates in response to treatment is sensitive, but the degree of change is meaningless unless pre-treatment detrusor pressure in known.

Quality of life

The AUA symptom score, its derivative the IPSS and the ICS questionnaire are the only ones to include some assessment of the effect of urinary symptoms on everyday life. The DAN-PSS-1 includes the bothersomeness of each symptom. The concept of the effect of symptoms and treatment on quality of life is becoming increasingly important and this aspect should be addressed in outcome studies.

Costs

As healthcare resources are limited and "clinical BPH" is a common condition, outcome studies must include an assessment of relative costs. Costs are not, strictly speaking, an outcome measure. An economic evaluation needs to be collected from the viewpoint of the patient and society and then combined with effectiveness to give an indication of the cost-effectiveness of different treatments.

Complications and durability

Treatment complications and durability of a specific treatment must also be addressed in a complete outcome evaluation of any treatment.

Duration of a treatment is also important as a cost effectiveness parameter. Issues like re-treatment rate, treatment failure rate etc. should also be considered.

Conclusion

Measuring of outcomes in "clinical BPH" depends on the purpose of the measurement. In the study of new treatments, all aspects must be covered. Parameters that are claimed to be affected must be investigated properly. A validated symptom score must evaluate symptoms, prostatic obstruction must be evaluated by pressure-flow studies, and quality of life and cost issues should be addressed. Other critical issues are the length of follow up and the long -term effectiveness of treatments.

In a quality assurance program outcome could be assessed in a less ambitious way using changes in a validated symptom score and changes in an indirect measure of outlet obstruction like urinary flow rate and/or residual urine volume. Impact on quality of life and the costs of treatment should be considered. The parameters used in everyday practice will depend on the facilities available to the practitioner.

MANAGEMENT OF INCONTINENCE IN THE MYELODYSPLASTIC CHILD

(The Association of Southern Urologists (USI – SZ) held its Annual conference at the Sri Ramachandra Medical College, Chennai, in August. Every year, the "Khivraj Memorial Symposium" is the high point of the conference. This year's symposium was on Neurovesical dysfunction, and the panellists were drawn from Bangalore, Chennai, Hyderabad and Manipal. Dr. Nitin Kekre from C.M.C. Vellore was the Convenor. We bring you some excerpts of the symposium – Editors)

Children born with Myelodysplasia form the largest segment of patients with Neurovesical dysfunction. The condition poses several problems in the child's social development. It also poses some serious medical problems in the long term. Urinary incontinence in these children may be worsened by the presence of bowel incontinence. Over a period of time, these children run a risk of silent upper tract damage due to bladder overactivity, lack of bladder compliance, vesico-ureteric reflux, recurrent urinary tract infections of a combination of all the above. Faecal incontinence may contribute to a higher incidence of infections. In addition, incontinence will greatly impair the child's psychological and social development as it grows up. Incontinence can also seriously affect local skin hygiene.

Ideally the management of the urinary tract and bowel has to be initiated at birth. It is however important to remember that given the prevalent circumstances in our country, many of these children may seek medical attention at a much older age. Management of these children has to be directed towards the preservation of renal function & promotion of continence. The causes of urinary incontinence are bladder overactivity, absence or inadequacy of sphincter function, or sphincter dyssynergia. Poor bladder compliance will worsen the picture.

A systematic approach will tell us what the underlying factors are, and management is then suitably directed.

Evaluation of a neonate

Where a diagnosis of myelodysplasia is made at birth, the following urological assessment is mandatory:

- Ultrasonography to assess kidneys for size and hydronephrosis, bladder wall thickness and post-void residue.
- Cystogram to evaluate form vesico-ureteric reflux and demonstrate any diverticulae

If closure of the neurologic defect is undertaken, it is mandatory to start clean intermittent catheterisation (CIC) immediately. CIC is also initiated where there is a large volume of residual urine – if one considers that the bladder capacity of a neonate, a residue of even 15ml is considered significantly large.

Urodynamic evaluation

Some teams advocate an aggressive urodynamic approach even in neonates. Besides the investigations mentioned above, a cystometrogram is performed to assess detrusor function and compliance. It is combined with sphincter electromyography (EMG) to document sphincter activity and synergy. A regime of CIC is then started irrespective of the bladder behaviour, and continued until more informative urodynamic assessment can be made at an older age.

A less invasive approach may also be followed, where the child is allowed to void spontaneously. This is permissible only if:

- Bladder wall thickness is normal
- There is no vesico-ureteric reflux
- Residual urine volume is less than $^{1}/_{3}$ bladder capacity for age
- Neural defect closure is not planned, or not necessary

Crede's manoeuvre is to be avoided as it elevates bladder pressures to high levels and can precipitate detrusor overactivity. Neonates already demonstrating upper tract changes, reflux or elevated serum creatinine levels have to be managed aggressively with anti-cholinergics and intermittent catheterisation.

Intervention

Intervention is necessary in the following situations:

- Deranged renal functions
- Upper tract changes, with or without reflux
- Poor bladder compliance or hyperreflexia on Urodynamic evaluation

If the first two are seen, a Vesicostomy is performed. If only the third is present, the child is started on anti-cholinergic medication and CIC, with a more intensive monitoring regime.

Follow-up consists of monitoring Serum creatinine, Urine culture, Upper tracts and residual urine at 3 months; 6 months; 9 months & 12 months of age. Thereafter, these tests are repeated annually until the age of 5 years when intensive urodynamic evaluation can be undertaken. If there is deterioration in these parameters at any time during the follow-up, urodynamic evaluation becomes mandatory.

Evaluation of older children

Most children in our country seek attention around the pre-school or school going age. Most of them have established incontinence; some have upper tract changes in addition. A detailed voiding history is taken. Wherever incontinence is present, the type and quantity is ascertained. This "voiding diary" is very important in the long run, and should be given its due importance.

Along with Renal function tests and Ultrasound, detailed urodynamic tests are performed. This includes a complete Cystometrogram (CMG) with sphincter EMG and video-urodynamics where available. A less invasive option is Uroflowmetry combined with sphincter EMG; this, however, falls short of the ideal on many counts. Information about the bladder will not be available, and this is vital in children with upper tract deterioration.

Urodynamic interventions in Myelodysplasia

While a very small percentage of myelodysplastic children may have normal bladder functions, the rest have one or the other of the following urodynamic abnormalities:

- Poor bladder compliance
- Detrusor hyperreflexia
- Detrusor-sphincter dyssynergia
- Sphincter denervation – Partial or Total

It is important to remember that detrusor dysfunction, dyssynergia and poor compliance can be present without evidence of bladder wall thickening or upper tract changes.

Where poor compliance or hyperreflexia is seen, the child is immediately started on anti-cholinergic medication and intermittent catheterisation. A voiding diary is maintained to assess efficacy of treatment. Upper tracts are monitored. Intervention for Vesico-ureteric reflux (if present) is not undertaken immediately; it can wait until bladder compliance has been restored.

If sphincter-dyssynergia is present, the cornerstone of management is intermittent catheterisation (CIC). Spontaneous voiding, or Crede's manoeuvre should be avoided, for reasons mentioned earlier. If dyssynergia is associated with poor compliance or hyperreflexia, anti-cholinergics are added to the regime.

Where sphincter denervation is the issue, the strategy for management is based on

1. Whether the bladder factors are normal;
2. Whether the denervation is partial or complete.

Bladder compliance and hyperreflexia have to be normalised before the sphincter is labelled inadequate. Anti-cholinergics are used to achieve this. If incontinence persists inspite of this, the sphincter is assessed with documentation of EMG and leak point pressures. If only partial denervation is present, urethral-lengthening procedures (like the Kropp procedure) will help. If total denervation is present, an artificial urinary sphincter is the only option.

Incontinence aids

The use of aids is strictly restricted to those children who have stable bladders, normal compliance and normal upper tracts. Incontinence in them would

therefore be purely due to sphincter denervation. Clamps and occlusive devices of any sort have to be condemned. They are painful. They are dangerous and can permanently injure the urethra and penis. Any aid should therefore be non-occlusive, easily applied, easily changed and preferably disposable.

Till such time as the child is ready for surgery, diapers and absorbent pads will not only keep the child dry, they will also ensure that no odour is present. These are freely available commercially. They can also be fashioned out of locally available, low-cost material or soft cloth. The child's social environment can be kept normal. Schooling is possible. Skin protection can be ensured. The first step in the management of these children would have been successfully taken.

(The concluding part will appear in the next issue of ICON – Editors.)

GOOD URODYNAMIC PRACTICE, GUP"

(We had carried the first part of Werner Schafer's article in our May 1999 issue. In the concluding part, he deals with standardisation of the measuring tools like catheters and transducers, calibration, display of parameters online, etc. - Editors)

INVASIVE URODYNAMICS:

Intravesical and Abdominal pressure recording

Any invasive urodynamic procedure requires careful indications with clear definition of the specific urodynamic question(s) to be answered. This will usually only be possible after completion of a bladder diary and free uroflowmetry. We will list some key aspects to be considered for a successful urodynamic study.

A good urodynamic investigation should be performed interactively with the patient and requires continuous conscientious observation of the signals. The aim must be at first to avoid artefacts and next to correct all of them at an early stage during the investigation. To correct artefacts during retrospective analysis is the worst solution. Artefacts are recognised at an early stage, when the signals are continuously observed and tested at regular intervals.

Urodynamics requires a special theoretical training and practical experience with equipment and procedures, with plausibility and quality control of urodynamic signals and their analysis. Because urodynamics deals largely with mechanical parameters such as pressure and volume and their related changes in time it is indispensable to understand the nature of these parameters, in particular pressure and flowrate. Therefore, in addition to comprehensive understanding of anatomy and physiology some basic knowledge of biomechanics and physics is indispensable.

A common problem in urodynamics is that clinicians often proceed straight-forward to a clinical interpretation, a) without critical analysis of the potential pathophysiological information content and plausibility of the signals, b) without considering the biomechanical context of their measurement, and c) without considering the physical properties of the parameters, technical limitations and accuracy of the signals.

Recommendation : It is unacceptable to perform invasive urodynamics without careful indication and a well defined urodynamic question, i.e. a question to be answered with the results from the urodynamic study.

Recommendation: The adherence to the ICS standardisation of zero pressure and reference height is strictly enforced. Zero pressure and reference height are terms which are often confused in urodynamics (possibly because the ICS Technical standard use the term: zero reference height). However as both are actually independent features of pressure, they must be kept clearly separated, and both must be taken into account strictly according to ICS standardisation. It is often argued that it does not make a difference for the most relevant parameter, P_{det}, if the same error is introduce to P_{ves} and P_{abd} as both tend to cancel out. This may often be the case. But many important aspects of quality and plausibility control are based on the recorded pressures and cannot be used if these are not recorded according to ICS standards.

Recommendation : We do not recommend use of microtip transducers for intravesical or rectal pressure recording. Microtip transducers have become popular due their apparent independence from hydrostatic pressure, and also due to the widespread misuse of zero balance. However, MTCs are unable to register a hydrostatic pressure correctly as their (the transducer's) reference height remains undetermined. This hydrostatic pressure is real and important, and inevitably plays

a role in any intra-corporeal pressure recording, in particular when two pressures are subtracted. It is obviously difficult to position an intravesical and a rectal MTC at any common level, particularly not at the level of the symphysis pubis, or to correct for any offset.

Recommendation: Catheters should be as thin as possible, e.g. 6F double lumen, only limited by practical aspect of placing it and by internal lumen size as is critical for filling rate and damping of pressure transmission. Both catheter channels are to be tested. As a standard we suggest use of a double lumen transurethral catheter. Only in children and patients with severe constrictive obstruction a supra public pressure recording may have advantages.

The use of two separate tubes for filling and recording is not meaningful. When after filling the (larger) filling tube is taken out for voiding it may appear of advantage when only an extremely small tube is left in the urethra. However, there is no data available to suggest that in a compressive obstruction such as BPH a 6F catheter has any influence on the study data which could be avoided by using a smaller tube. But there is a lot of data suggesting that a single study is not recommendable; therefore, with the catheters in place, a voiding study should be repeated at least once to control reproducibility. Re-introduction of the separate filling tube for a repeated study is more invasive and complicated.

Recommendation : For abdominal pressure recording we suggest use of a rectal balloon catheter. Although there may be various procedures to successfully record abdominal pressures, a flaccid balloon gives a suitable signal to determine a meaningful Pdet from Pves. The recording of P_{abd} only serves as a measure to eliminate the impact of abdominal on intravesical pressure. The role of the balloon is only to avoid blockage of pressure transmission to the transducer or, as the rectal ampulla is usually not a homogeneously filled space, to prevent recording of a local contact pressure which is not representative of the abdominal pressure. This function of the balloon is best achieved when the balloon is filled to not more than 10-20% of un-stretched capacity. Overfilling and elastic distension of the balloon is the most common mistake in rectal pressure recording. It is obvious that microtip transducers are not suitable for recording pressure in a non-homogenous surrounding such as in the rectum with multiple reasons for direct impact on the transducer.

EQUIPMENT: MINIMUM REQUIREMENTS

Definite technical standards are not yet specified. Some aspects will be discussed here.

Recommendation : The standard today is a PC-based urodynamic system allowing simultaneous measurement, display, and secure storage of at least 2/3 pressure channels with a flow/volume channel:

1) two pressure measuring channels and one flow rate or volume;
2) displaying on printer and/or monitor 3 pressures (P_{abd}, P_{ves} and P_{det}) and as tracings over time, filling and voided volume as numbers.
3) With documentation of additional comments.

The information must be displayed and documented with adequate scale and resolution; no information should be lost when tracings go off-scale.

Recommendation :

1. Accuracy of 1cm H_2O for pressure and +5% relative for flow and volume; Ranges : 0-250 $cmH_2O$for pressures; 0-25 (50) ml/s for flow; 1000 ml for volume.
2. The software must make sure that no information upto 250 cmH2O and 50 ml/s is lost internally even when not displayed externally, and that off-scale values are clearly identified.
3. an AD frequency of 10 Hz per channel is sufficient for pressure and flow; for EMG recording a higher frequency (up to 20 kHz) may be necessary.
4. Calibration of all signals should be possible.

Calibration

The question of need for calibrating pressure transducers, flowmeter, and pump cannot be answered in a simple Y/N fashion. The specification of the manufacturer should be studied. Two aspects must be considered: 1)the intended accuracy and 2) the experience with the same system and supply over some period. It is desirable to regularly calibrate the system and take careful note of the results. Calibration for pressures should not be confused with simple “zero balance”, which is only one aspect of calibration. In addition to setting the zero, it must possible also to check and adjust the amplitudes of all measurement channels, i.e. calibrate all signals.

Calibration of the flowmeter can be achieved by pouring a precisely measured volume at a rather constant flow in the typical range, e.g. 400 ml at 15-20 ml/s, i.e. in 20-30 seconds into the flowmeter, and checking the readings for flow rate and volume. Similarly one can test the pump by measuring the time to pump e.g. 100 ml into a measuring cylinder. If small calibre catheters are used, it may be necessary to perform the pump calibration with the catheter connected.

Recommendation : A meaningful quality control is only possible when the measured signals are displayed in analog form as curves over time together with derived signals continuously and without delay while the examination is performed. Additional parameters such as filling and void volume can be displayed as curve or digitally as number. All curves and numbers should be labelled according to ICS standard with complete and clear scaling of amplitude and time axis.

Recommendation : On-line documentation of comments should be possible. If necessary intervention, i.e. interruption, manipulation, and continuation of the measurement and recording should be always possible.

Recommendation: The scales should be kept unchanged as much as possible, because urodynamic data quality control is based on pattern recognition, and the recognition of pattern depends on scale. During recording and for analysis, we suggest a scale of 40 (or 50) cmH2O per cm and 10 ml/s per cm for the amplitudes, and 1 minute per cm or (5 seconds per mm) for the time axis during filling and 1 second (or 2 seconds) per mm. during voiding

Urodynamic measurements should be documented as curves over time with comments and explanations, so that a retrospective judgement of curve is possible. A documentation of urodynamic measurements with few numerical values alone is usually insufficient. For documentation the same amplitude scale should be used but the time axis may be compressed if relevant information is not lost due to poor resolution, e.g. 2 minutes per cm (or 10 seconds per mm) during filling and 5 seconds per mm during voiding. Full scales of 200 cmH_2O, 50 ml/s and 1000 ml are sufficient. Line resolution should be better than 0.10 mm.

Display & Report

Recommendation: The following sequential position of tracings is suggested: P_{abd} at the top, then P_{ves}, P_{det} and voided volume (Q). If tracings are superimposed, we suggest: P_{abd} with P_{ves} and P_{det} with Q. This requires coding of tracings by colour or pattern. Additional EMG tracings should go with P_{det} and Q. Volumes are sufficiently displayed as numbers.

RESEARCH - PACEMAKER CELLS IN URINARY TRACT

Researchers from the University of Pittsburgh Medical Center UPMC, Dallas have reported the discovery of cells in the urinary tract that influence the process and timing of urination. Their research findings, which could lead to therapies for various urologic problems, was presented at the American Urological Association 1999 annual meeting. These so-called pacemaker cells, which have been speculated to exist but have never before been identified, provide insight into a variety of urinary conditions.

These system of cells, known as Interstitial Cells of Cajal (ICC), have been found to control movement of solid waste through the gastrointestinal tract. Similar cells were also found to exist in female mice studied by the UPMC researchers. Specifically, they were found in the ureters, bladder and in the urethra.

According to lead investigator Michael B. Chancellor, M.D., Associate professor, Urologic surgery at the University of Pittsburgh School of Medicine “Such a finding has tremendous implications for all sorts of urinary problems. We might be able to treat some conditions by encouraging production of more of these cells, and treat other conditions by curbing their over-abundance”.

It is being hypothesised that reduction in the number of these cells could explain some very common problems, such as primary bladder neck obstruction. As a corollary urinary incontinence could be caused by too many of these pacemaker cells in certain parts of the urinary tract.

Annual Meeting of
the International Continence Society
28 August 2000 to 31 August 2000
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ABOUT THE FOUNDATION

The Indian Continence Foundation (I.C.F.) is the Indian affiliate of the International Continence Society. It is constituted with the following objectives:

- To create an awareness among members of the public about the problem of incontinence and incontinent people.
- To provide for the scientific care of incontinent persons through training of care-providers and family members in the same.
- To desseminate knowledge about the various incontinence aids, appliances & devices available to patients of incontinence
- To procure these for patients at concessional rates through interaction with manufacturers.
- To promote the latest medical developments in the field of incontinence among Doctors, Nurses and para-medical personnel.
- To provide a forum for patients and family members to interact and solce social and emotional issues of mutual concern.

In order to fulfil these objectives, the foundation has an elaborate schedule of activities. Some of them are

- Newsletters on current developments on incontinence catering separately to Medical personnel.
- Workshops for Nurses & Care-providers to impart training in the care of incontinent patients.
- Public lectures, Seminars and interactive discussions on topics of relevant concern
- Establishment of a database of Incontinent patients with a view to evolving long-term policies for the prevention of Incontinence.

If you wish to be a part of this endeavour, please contact the President or Hon. Secretary of the foundation for a fact sheet and other details. Individuals, Organisations as well as Corporate bodies are welcome.

The Indian Continence Foundation is organising a course "Current Management of Incontinence" for Nurses and Care-providers on 27th and 28st November 1999 in Bangalore. It will be an interactive platform of Lectures, Demonstrations and practical problem solving sessions For further details kindly contact

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This Publication is supported by an Educational Grant from
Pharmacia & Upjohn

Printed and published on behalf of

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