NEWSLETTER

SA Urogynaecology Association

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Editorial

Thanks to Dr Zeelha Abdool for the excellent newsletter this quarter - she has collected a fine bouquet of articles from several of our expert colleagues. As usual, they are interesting and informative, but above all of practical importance.

As we commence a new year it is sobering the reflect that in only 2 years from now, we have the major IUGA meeting here in Cape Town. I urge you all to keep July 2016 open, so you can make the journey.

Peter de Jong

Editor

Informed consent

Peter de Jong

Informed consent still remains one of the primary reasons medical specialists have to attend disciplinary hearings at the HPCSA (ref: HPCSA guilty verdicts Jan-Dec 2012). Informed consent should be viewed as an ongoing process rather than a single event and should address all standard operating procedures. Please remember that patients have to consent even to the fact that ICD-10 codes are submitted to funders.

In terms of consent for surgical procedures, we are reminded that any procedure envisaged should be discussed with the patient together with the expected result(s) (cosmetic and functional) of the procedure. The patient should be given a general idea in broad terms and layperson's language of the nature, scope, consequence, risks, dangers, results, complications, benefits, disadvantages and prognosis of a treatment, as well as the alternatives to proposed intervention. All serious risk factors and significant dangers to the patient should be mentioned.

If laparoscopic procedures are undertaken, archive the images in the patient's folder.. Write an account of what is discussed, and document all relevant facts. This all takes time, but is well worth the effort if the lawyers ever take an interest in the case.

SAUGA committee

Leader article from the guest editor

Overactive Bladder: When medical treatment fails

Dr Zeelha Abdool

Overactive bladder (OAB) is a term used to describe the symptom complex of urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI), in the absence of urinary tract infection or other obvious pathology. It is associated with a significant negative impact on various quality of life domains. The need to plan daily activities, wear incontinence pads/ nappies, toilet map, associated depression and social isolation is well documented. Although pharmacotherapy in combination with conservative therapy (pelvic floor exercises. lifestyle changes, bladder retraining) is recommended as first line treatment, poor adherence rates therapy of up to 80% is recorded. Patient's that are refractory to medication are often referred to tertiary institutions for further assessment, investigations and management. Alternative treatment offered includes Botulinum toxin, neuromodulation (central, peripheral, cutaneous) or reconstructive surgery in rare circumstances.

Botulinumtoxin: In 2011 the FDA approved the use of intravesical Onabotulinumtoxin A for the treatment of neurogenic urge urinary incontinence. This neurotoxin is derived from the anaerobic bacterium *Clostridium botulinum*, and is thought to inhibit the release of acetylcholine (Ach), adenosine triphosphate (ATP), and substance P from the urothelium, leading to detrusor paralysis with a consequent improvement of symptoms. A number of proprietary preparations of botulinum toxin type A are commercially available (each with differing pharmacokinetics and dynamics) and are thus not interchangeable. Although type A has been more popular, botulinum toxin type B has also been shown to improve symptoms but for a shorter duration. Robust data from RCT's are lacking due to heterogeneity in dosages, patient selection, procedure protocols and reported outcomes. For urgency urinary incontinence (UUI), observational studies have reported improvements in the range of 36-89%, 65% reduction in UUI episodes and complete continence in 58%.The benefit after a single injection is reported to last for approximately 6 months, and this depends on the dose, site and depth of injection. Although this treatment option works well in selected patients, dose related voiding difficulties, need for self catheterization, distant muscle paralysis and recurrent urinary tract infections have been reported.

Neuromodulation: Neuromodulation may also be used in women with refractory symptoms. Sacral Neuromodulation (central), percutaneoustibial nerve stimulation (peripheral) and cutaneous neuromodulation are available. Sacral neuromodulation (SNS) was first introduced in 1997 and just over 50 000 patients have received this device. The surgically implanted lead and generator stimulate the S3 sacral nerve root, and it is postulated that it resets the afferent pathways that control micturition in the spinal cord. After the test phase which determines the patients' therapeutic response, permanent implantation takes place.

The test phase may either be an in-office temporary lead placement or an outpatient surgical implantation of tined leads. A 50% improvement in the test phase is usually regarded as a favourable response. Many studies have shown SNS to be effective for OAB treatment using a cut off of 50% symptomatic improvement in clinical symptoms to define success. The reported success rates at 5 years is between 50- 62%. This procedure requires careful patient selection and appropriate patient counselling. Commonly reported adverse events include: pain at stimulation site/lead site, lead migration, infection, electric shock and the need for surgical revision (up to 30%). Other limiting factors include passing through airport metal detectors, and inability toperform MRI's (implanted devices). Cognitive impairment, great cost and need for future MRI's limit the use of this treatment modality.

Percutaneous tibial nerve stimulation is a method of peripheral neuromodulation. PTNS was approved by the FDA in 2000 for UUI, and for OAB in 2010.The mechanism is similar to that of SNS, targeting S2-4 afferents via the tibialneve. The procedure involves insertion of a 34-guage needle approximately 3-4cm cephalad to the medial malleolus of the either ankle. After the application of a surface electrode to the arch of the chosen foot, the needle and the electrode are then connected to a low voltage stimulator. The current is increased gradually until you observe fanning of the toes or curling of the big toe. Sessions last for 30min and repeated weekly for 12 weeks. Two RCT's,SUmit and OrBIT have been performed to evaluate PTNS. The SUmit was a double blind placebo controlled study which compared PTNS (n=103) to sham needle placement (n=105).There was a significant improvement in UUI and quality of life. The first phase of the OrBIT trial reported similar results (using the voiding diary) between PTNS subject (n=41) compared to 4mg extended release tolterodine (n=43). At 12 weeks, both groups reported a decrease in the number of mean voids per day, decrease in UUI, but the PTNS subjects did have a greater subjective impression of improvement compared to the tolterodine subjects (79.5% vs 54.8%, p=0.01). Phase 2 of the OrBIT found sustained positive effects in UUI improvement at 6-12 months in subjects that continued PTNS. There are minimal adverse effects reported with PTNS such as needle discomfort, tingling in the legs, and bleeding at the needle site. The STEP study which is an extension of the SUmit trial reported sustained effects at 24 months (n=35).

In summary, PTNS is a relatively low risk treatment option in patients refractory to first line treatments, have intolerable side effect due to antimuscarinics and for those who decline or cannot afford to have an implantable device. Further studies are needed to evaluate whether PTNS is an acceptable office procedure for women in the long term.

Recently a non-invasive, patient managed neuromodulation system (PMNS) has been developed. The device transmits a transdermal wireless signal via a disposable adhesive patch that it applied to a precise location over the sacral area once a week. More studies are required before its introduction into clinical practice.

Reconstructive surgery: Finally, augmentation cystoplasy and supravesical urinary diversion(with cystectomy) can be considered for those refractory to above mentioned options. Ileocystoplasty is the most common bladder augmentation procedure, and the considerable associated complications are well noted. Patients who opt for urinary diversion must commit to intermittent self catheterization.

Conclusion: The treatment modalities for OAB will continue to evolve, as evidenced by the new B3 adrenoceptor agonist, Mirabegron.Although a small number of patients have been studied, it appears to be effective and well tolerated. It is not yet available in South Africa.Neuromodulation options now offer patients effective and less invasive treatment alternatives. Over the next few years we are certainly going to read more about the identification of novel diagnostic, prognostic and predictive urinary biomarkers in OAB which will revolutionize our approach to OAB.

References available on request

Urethral Diverticula – Fact or myth?

Prof Frans van Wijk

Urethral Diverticula in women is a condition that is rarely diagnosed at presentation and gives long term symptoms which can significantly affect the quality of life of the patient significantly.
The "myth" of a urethral diverticula lies in the fact that the incidence is unknown. Currently the incidence is estimated in between 0.6% to 6% of woman.

The reason for the under diagnosing for the urethral diverticulum – is the fact that it seldom presents with the typical triad of dysuria, dyspareunia and dribbling.
The most acceptable theory about the pathogenesis of urethral diverticula is infection of the small glands around the urethra, which forms an abscess and sometimes the glands can confluence and form a bigger cavity.

This then would rupture thought the area of lower, lowest resistance, which is mostly the urethra and forms a small ostium where puss can drain into the urethra and urine can pass into the diverticulum. More than one ostium is possible but rare.

The pathology of the urethral diverticulum is a facial layer around the true diverticulum. This is on the inside covered urothetium. The configuration of the diverticulum varies widely from a single round cavity to a horse-shoe formation that extends almost right around the urethra.

The clinical presentation of this condition can include lower urinary tract symptoms if not the triad of dysuria, dyspareunia, and dribbling.
The patients can also present with a tender vaginal mass or sometimes hematuria and recurrent bladder infections. Diagnosis is most commonly made by clinical assessment of the patient by feeling the mass, and if puss can be expressed from the diverticulum into the urethra, the diagnosis is almost certain.

SPECIAL EXAMINATIONS

Recent advances in pelvic ultrasonography increased the diagnostic power of this modality greatly.

The gold standard is still the MRI which demonstrates the diverticulum clearly. A positive pressure urethrogram can be used for the diverticulum, and there are different catheters that can be used to block the meatus and the bladder neck to create high pressure in the urethra.

The differential diagnosis includes: Urethrocoele as well as cystic or solid masses arising from tissue in and around the urethra.
Malignant changes in the diverticula might occur (although very rare) and this might include adeno carcinoma, transitional cell carcinoma or squamous cell carcinoma.

TREATMENT OF DIVERTICULA

Non-surgical treatment is mostly indicated in patients who are pregnant or have a high risk for complications due to the surgery and few symptoms of the diverticulum.
In some cases aspiration can be done to relieve the symptoms, until the patient is in a better physical condition.

SURGICAL MANAGEMENT

Endoscopic management of the diverticulum includes trans- urethral incision and electro cauterization of the wall of the diverticulum.

This might be a good alternative if the diverticulum is accessible through the urethra, and has got a low risk of fistula confirmation and incontinence. Formal transvaginal excision of the fistula is still the gold standard.

The incision lines must not overlap and a u-incision is mostly made. The peri-urethral fascia is then opened to get to the true diverticulum.

This is excised completely and the difficult dissection planes are the distal urethra, bladder neck and lateral recess of the diverticulum.

The ostium is closed, if there is loss of tissue a Martius flap provides excellent bulking to improve vascularity.

Avoid doing any incontinence procedures with the repair of the diverticulum. It might be necessary on a later stage to do incontinence procedures.

POST OPERATIVE CARE

The patient is covered with antibiotics perioperatively.
A catheter is left for 10 days to 2 weeks and a voiding sisto- urethragram is done to confirm the success of the procedure.

POST OPERATIVE COMPLICATIONS

Complications include urethra vaginal fistula, recurrence of the diverticulum, stress urinary incontinence and urethral strictures.

These complications must be evaluated and then treated accordingly to the situation.

Comments from our Readers

Letter from Dr Winer, Editor of the SA Journal of fetal and Animal Physchairy

"I note you have no pictures In your newsletter. Please can you publish some pictures".

Comment from the Editor: You are quite correct, Dr Winer. Here is a fine picture of the founder of the UCT female continence clinic, Prof D Davey, at the first clinic established in Groote Schuur Hospital.

From the Editor's collection

Non-mesh treatments for stress incontinence

Dr Paul Swart

Not all patients that present with stress urinary incontinence (SUI) would be suitable candidates for sub-urethral mesh slings, nor would some patients desire a surgical solution to their symptoms. Although sub-urethral slings using mesh has revolutionized the management of SUI, other options might be appropriate management in certain circumstances.

Some lifestyle changes might improve the incontinence to such a degree that quality of life is restored and surgery would then not be necessary.

Weight loss

Numerous studies have confirmed the efficacy of weight loss in managing SUI. In obese patients the weight loss is more effective as a form of therapy but even patients that are moderately overweight will improve with losing weight. In one study 338 women with a mean BMI of 36 kg/m2 and SUI were compared to a control group. The study group lost 7.8kg on average and the control group 1.2kg. Weekly incontinence episodes decreased by 47% in the study group and 28% in the control group. I do not know of any study that came to contrary conclusions.

Fluid intake

Excessive fluid intake can contribute to incontinence, more so with urge incontinence but also with SUI.

Behavioral treatment

Bladder training and pelvic floor muscle exercises (PME) are effective treatments for both urge and SUI and obviously then also for mixed incontinence. Frequent voiding to keep the bladder empty will alleviate the impact of SUI. PME, properly done, increases the effectiveness of the urethral closing mechanism. Healthcare professionals should oversee these programs, preferably with biofeedback and perseverance by the patients. PME is more effective in younger patients.

In a recent study it was shown that sub-urethral slings were significantly better than PME although 64.4% of women in the PME group had subjective improvement in SUI symptoms. The wonderful thing about PME is that there are no side effects or complications. PME should be the first mode of therapy offered to particularly young women with mild to moderate SUI.

Pessaries

This modality is probably under utilized as it has been shown to be as effective as behavioral therapy. Some expertise and experience is needed but complication rates are very low.

Protective clothing

Can be expensive but can certainly make a big difference in quality of life of SUI sufferers.

Duloxetine

Duloxetine is a SNRI and not infrequently used in Europe for the management of SUI. Variable results are reported with some studies finding no difference from placebo. About 20% of patients will discontinue use due to side effects such as nausea.

Surgical procedures other than slings:

Burch Colposuspension:

This is a good procedure for SUI but not easy to perform and it has the disadvantage of increasing the chances for posterior compartment prolapse. This procedure however is less likely to induce urge than a urethral sling procedure. It is a viable option in patients that have to undergo abdominal procedures for other reasons such as a hysterectomy.

Bulking agents:

Have been shown to be effective as primary and secondary salvage procedures. As primary treatment it is less effective than urethral slings and can complicate later surgery. It is mainly used as secondary procedures after sling operations with residual SUI.

Other procedures of historical interest

Anterior colporrhaphy with or without a Kelly plication give inferior results to sling procedures.

Paravaginal repairs for SUI is inferior to Burch procedures and slings for SUI.

Trans-vaginal needle suspensions such as Raz and Stamey should not be performed any longer as they have results inferior to colposuspensions and slings.

Marshall- Marchetti-Krantz (MMK), where the endopelvic fascia next to the bladder neck is suspended to the retropubic periosteum, is no better than colposuspension and leads to considerably more complications.

Tissue modifying therapies:

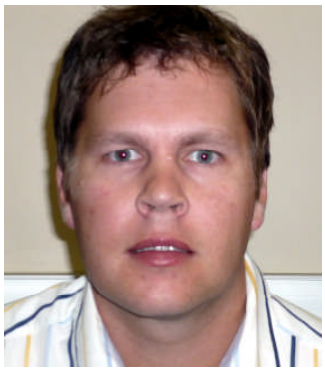
Estrogen, either orally or vaginally is no treatment for SUI and oral estrogen has been shown to increase the prevalence of SUI.

Laser modification of peri-urethral tissue has been shown to be effective in improving SUI. Erbium:Yag laser energy is used in the vagina and has been shown to be safe with good results for both incontinence and pelvic organ prolapse. Long-term studies are lacking but promising poster presentations have been presented at IUGA.

The use of Mesh Implant in Vaginal Prolapse Surgery:

Position statement and recommendations of the South African Urogynaecology Association

First version 2012 Current update 2014



Dr Etienne Henn

Introduction:

Pelvic organ prolapse (POP) is affecting more and more women. This is evident in an ageing world population and current data showing that the lifetime risk for such surgery is 20% at age 80 years. The use of transvaginal mesh for the correction of POP has seen exponential growth worldwide and also in South Africa over the last 8-9 years. This has however been reigned in after an FDA health warning was issued in July 2011. This warning along with the now required post-marketing surveillance studies has led to some manufacturers having withdrawn wholly (Johnson and Johnson) or partially (Boston Scientific, CR Bard) from the market. Anecdotally the overall use of vaginally implanted mesh in the USA has fallen by 40 – 60% since the 2011 FDA announcement.

SAUGA position summary:

The SAUGA supports the use of transvaginal mesh in individually selected cases. Patients need to be evaluated individually on the basis of amongst others their tissue quality, type of prolapse, previous surgery, and co-morbidities. An adequate informed consent process has to be followed and surgeons are required to possess sufficient basic anatomical and surgical knowledge and experience prior to embarking on the use of transvaginal mesh for the correction of POP. The full position statement with recommendations on the use of mesh is available on the website: www.sauga.org.za.