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ORIGINAL ARTICLE

Surveillance of bladder management in a local cohort of neuro-urology patients

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BACKGROUND

Several neurological conditions, including multiple sclerosis and spinal cord injury, can give rise to a neurogenic bladder. Without proper management and regular surveillance, the sequelae of a neurogenic bladder can be devastating, including recurrent urinary tract infections, urolithiasis, and worst of all, renal failure, all of which continue to negatively impact these patients' quality of life. There are two main guidelines available, developed by the European Association of Urologists (EAU) and National Institute of Clinical Excellence (NICE), to aid clinicians in the management of these patients. While both guidelines promote patient risk stratification into high and low risk categories for renal complications, there are several areas of discordance between them.

METHOD

In this retrospective audit, 58 neuro-urology patients who underwent video-urodynamics within a 6-year period were included, to determine whether they were properly followed-up, according to their risk category, as per the NICE guidelines.

RESULTS

Surveillance rate in the local cohort of neuro-urology patient was low. This could be attributed to the differences between the two guidelines, creating doubt and hesitancy in decision-making in the caring urologists, thus making their application in clinical practice more difficult. Other contributing factors include the lack of proper registries, and the lack of international evidence-based literature in the field.

CONCLUSION

Through this audit, we aim to emphasise the importance of further international research, as well as, creating a neuro-urology patient database within the local National Healthcare System (NHS) to ensure an optimal surveillance process.

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INTRODUCTION

Neuro-urology lower urinary tract symptoms (LUTS) secondary to a Neurogenic bladder may occur due to a number of underlying neurological diseases or events including Spinal Cord Injury (SCI), Spina Bifida (SB) and Multiple Sclerosis (MS), with the type of symptoms depending on the level and extent of the lesion.[1] Renal failure is one of the main mortality factors in patients with Neurogenic bladders, with for instance around 13% of SCI patients dying as a consequence of urological complications.[2] Therefore, maintaining what is known as a safe bladder is a top priority in the treatment of patients with a Neurogenic bladder.[1] A safe bladder refers to a bladder with detrusor pressures during both the filling and voiding phases within safe limits, and with normal compliance; and therefore, a bladder which does not put the patient at high risk of renal function deterioration.

There are a number of international guidelines which aim to guide the caring team in the management of the neurogenic bladder including the European Association of Urology (EAU) guidelines on Neuro-urology[1] and the National Institute for Clinical Excellence (NICE) CG148 guideline entitled Urinary Incontinence in Neurological Disease.[3] Both of these guidelines give guidance on initial assessment, management and surveillance of patients with Neurogenic bladders. However, whilst the EAU guidelines advise that Video Urodynamics (VUDs) should be performed in the assessment of all patients with neurogenic LUTS, the NICE guidelines suggest stratifying patients into those with a low risk of renal deterioration, and those with a high risk of renal deterioration. The latter group should be assessed with VUDs, whilst the former does not.

The NICE guidelines define patients as being at high risk of renal deterioration if there is at least one definite risk factor or two probable risk factors. Definite risk factors include a duration of MS of more than 15 years, presence of an indwelling catheter, high detrusor pressure on VUDs, and ample uninhibited contractions of the detrusor. The probable risk factors include detrusor sphincter dyssynergia (DSD) on VUDs, age over 50 years, and male sex. Patients with hydronephrosis on imaging, a febrile urinary tract infection or evidence of acute urinary retention should also be classified, or re-classified as high risk.[3]

When it comes to surveillance, there is once again some discord between the guidelines. Whilst both guidelines advocate stratification into high and low risk groups for renal deterioration, the EAU guidelines leave the method of stratification at the discretion of the clinician. The EAU guidelines go on to advise lifelong follow-up with clinical review annually, and Ultrasound (US) of the Urinary Tracts at least once every six months in the high risk for renal deterioration group, together with regular urinalysis and annual blood chemistry. Whilst, in the low-risk group the EAU guidelines advise lifelong follow-up with clinical review at least every two years, and regular urinalysis, they also advise that any significant clinical change should prompt investigation and intervention.[1]

AIMS

The aim of this audit is to review local adherence rates to the EAU guideline surveillance protocols,[1] with risk stratification as suggested by the NICE guidelines,[3] in a local cohort of neurogenic bladder patients.

MATERIALS AND METHODS

This retrospective audit includes data on 58 patients who underwent VUDs at Mater Dei Hospital during a 6-year period. Data protection clearance was obtained prior to the start of data collection. All data was anonymised in a spreadsheet.

The data was collected by analysing all VUDs reports written between March 2015 and March 2021 by the performing Urology trainee or specialist on the local VUDs software. All patients above the age of 18 referred for VUDs in view of neuro-urology LUTS were included in the study. Patients which were deceased by March 2021 were excluded. Patient demographics, urodynamic parameters, imaging and serum or urine biochemistry results, and clinical follow-up appointment dates were manually retrieved from iSoft Clinical Manager and from the local VUDs software accordingly. The Maltese MS registry was also used to retrieve demographic data for patients with an underlying diagnosis of MS.

Patients were stratified into high and low risk for renal deterioration categories based on their demographics, imaging results and VUD findings. Patients were classified into the high-risk category as per the NICE guidelines protocol defined previously, or if their VUD findings indicated that the bladder was unsafe. A patient was categorised as having an unsafe bladder if there was VUD evidence of Vesico-ureteric reflux (VUR), poor bladder compliance or a leak point pressure (LPP) of >40cmH20.

Local adherence to surveillance protocol guidelines was then analysed by calculating percentage adherence to each recommendation, as mentioned previously, for the patients in the high risk and low risk categories. In this regard, data was collected from the date of the VUD study up to March 2021. For patients who underwent multiple VUD studies in the study period data was collected from the date of the most recent VUDs up to March 2021. Microsoft excel® software was used for statistical analysis tests. The standard referred to for surveillance protocol is the EAU Neuro-Urology guideline.[1]

BASELINE DEMOGRAPHICS RESULTS

59 patients were initially included, 1 patient had passed away in October 2018 and was excluded from the study. The 58 patients included had undergone a total of 68 VUD studies in the 6-year period, with 48 patients having undergone one study, 5 patients having undergone 2 studies and 3 patients having undergone 3 studies in the study period. 22, 18, 2, 7, 9 and 10 studies were performed in the first to the sixth study period respectively, with each period being taken as 12 months starting from March 2015 and ending March 2021.

The age of the patients recorded, was the age at the time of their last VUD study in the study period. The mean age of the patients included was 46.8. The youngest patient included in the study was 18 at the time of the VUD study and the oldest 79 years.

36.2% (*n*=21) of the patients included were female, whilst 63.8% (*n*=37) of the patients included were males. This lack of balance may reflect the fact that many underlying conditions for neurogenic bladders having a higher prevalence in the male population. For instance, spinal cord injury is around 3 to 4 times more common in males than females.[4]

The frequency of the various underlying conditions in the group is illustrated in table 1. The most common underlying conditions in the group were SCI, SB and MS which represented 24.1% (*n*=14), 22.4% (*n*=13) and 13.8% (*n*=8) respectively.

46.5% (*n*=27) of the patients were classified as high risk based on their demographic factors, imaging results or previously known urodynamic parameters. 15.5% (*n*=9) patients were classified as high risk based on the urodynamic parameters from the VUD study reports reviewed. This left 37.9% (*n*=22) of the patients in the low risk for renal deterioration category.

Table 1: Frequency of Underlying Neurological Conditions or Events resulting in Neurogenic LUTS

Underlying Neurological Condition or Event resulting in Neurogenic Bladder	*n=*	%
Post Abdominoperineal Resection	**1**	**1.7**
Cauda Equina Syndrome	**2**	**3.4**
Cerebellar Ataxia	**1**	**1.7**
Chronic Inflammatory Demyelinating Polyneuropathy	**1**	**1.7**
Disc Prolapse/Cord Compression	**7**	**12.1**
Cerebral Vascular Accident	**2**	**3.4**
Decompression Sickness	**2**	**3.4**
Devic's Syndrome	**1**	**1.7**
Diabetic Neuropathy	**1**	**1.7**
Post Laminectomy/Discectomy	**2**	**3.4**
Multiple Sclerosis	**8**	**13.8**
Spina Bifida	**13**	**22.4**
Spinal Cord Injury	**14**	**24.1**
Spinal Cord Infarct	**1**	**1.7**
Transverse Myelitis	**1**	**1.7**
Wolfram Syndrome	**1**	**1.7**

OUTCOME RESULTS

For the high risk for renal deterioration group, adherence to 5 recommendations put forward by the EAU neuro-urology guidelines was audited. These surveillance recommendations are that high risk patients should undergo lifelong follow up, clinical review annually, US every 6 months, regular urinalysis (which was taken to mean urinalysis annually), and annual blood chemistry (creatinine). Adherence rates to these recommendations were found to be 69.4%, 69.4%. 8.3%, 25% and 66.7% respectively. Table 2 illustrates these adherence rates graphically.

For the low risk for renal deterioration group, adherence to 3 recommendations put forward by the EAU neuro-urology guidelines was audited. These surveillance recommendations are that low risk patients should undergo lifelong follow up, clinical review every 2 years, and regular urinalysis (which was taken to mean annually). Adherence rates to these recommendations were found to be 63.6%, 72.7% and 18.2% respectively. Table 3 illustrates these adherence rates graphically.

Table 2: Adherence rates to EAU Surveillance Recommendations for High-Risk for Renal Deterioration Neurogenic Bladder Patients

Total High-Risk Surveillance *N*= 36			Adherence
Lifelong Follow Up	No	11	
	Yes	25	0.694
Clinical Review Annually	No	11	
	Yes	25	0.694
US every 6 months	No	33	
	Yes	3	0.083
Urinalysis every 6 months	No	27	
	Yes	9	0.25
Annual Blood Chemistry	No	12	
	Yes	24	0.667

Table 3: Adherence rates to EAU Surveillance Recommendations for Low-Risk for Renal Deterioration Neurogenic Bladder Patients

Total for Low-Risk Surveillance N= 22			Adherence
Lifelong Follow Up	No	8	
	Yes	14	0.636
Clinical Review every 2 years	No	6	
	Yes	16	0.727
Urinalysis Regularly	No	18	
	Yes	4	0.182

DISCUSSION

Continuous surveillance of bladder function in neuro-urology patients is imperative as disease progression may occur in a very short period of time.[5] In addition, there is very little correlation between disease severity and symptomatology.[6] Through regular surveillance, the effect of any intervention or change in management can also be assessed and other treatment options considered according to new findings.[7]

Even though the importance of surveillance is highlighted in most literature, the specific methods, timing and frequency are not clearly identified. This is attributed to a lack of international evidence-based research on the subject, as most of the available information is derived from retrospective studies and expert opinion.[8-9] The same issue applies to the local situation, whereby, to the authors' knowledge, there have been no local studies and audits on the management of neurogenic bladders up till now. This can also be related to the absence of registries compiling data on patients with neurogenic bladder according to their specific cause, therefore making patient follow-up very difficult. To date, the MS register is the only pertinent register available in this regard in Malta, and this was utilised in this audit to determine the year of MS diagnosis, for risk stratification purposes. Encouragingly, a new guideline on the bladder management in patients with spinal cord injury has recently been developed and published on the local clinical guideline database. This aims to guide the multidisciplinary team in the acute and long-term management of patients with neurogenic bladders secondary to spinal cord pathology.

The lack of surveillance in the local population could possibly be related to the discordance between the available international guidelines, leading to hesitancy from the clinician's point of view. Furthermore, in both the NICE and EAU guidelines, there are several areas of ambiguity, resulting in further uncertainty in clinical practice. One example is that both guidelines mention regular urinalysis as part of the surveillance protocol. However, neither define accurately the interval period. Subsequently, the interval was taken to be equivalent to 1 year in this audit, without any actual scientific basis. This, once again, can be attributed to lack of research on the subject. Another point to consider is that given the limited data available, clinicians are likely to adapt their surveillance method, frequency and duration according to the national healthcare system in which they practice. Although NICE is the more cost effective of the two guidelines, given that it is based on the British NHS, their actual clinical application is still limited by funds and resources available to the caring urologist.[10]

There were several limitations in this study. The most obvious one was the small number of patients involved in this audit, especially in the last 3 years of the study period. One reason for this could be that since VUDs is an invasive investigation, patients might not be willing to undergo the procedure. In addition, in view of the ongoing Covid-19 pandemic, many of the elective procedures, including VUDs were cancelled or postponed. Furthermore, in Malta, patients might be followed-up by Urologists outside the National Healthcare system (NHS), leading to patient loss from the database and missing surveillance data.

Another limitation was that in Malta, air-charged catheters are used during VUDs, while the ICS Standardised Urodynamic Protocol is based on water-charged protocols, leading to possible risk stratification errors. Additionally, since patient information and selection were taken largely from VUD reports, which are heavily operator-dependent, possible documentation errors could arise, again leading to inaccuracies in risk stratification. Another possible issue is that the indication for regular serum creatinine, urinalysis and ultrasonography might have been completely unrelated to the surveillance process, given that such patients have several co-morbidities, requiring multiple hospital admissions and follow-ups from other specialties.

CONCLUSION

Although both EAU and NICE guidelines are very useful aids to the caring Urologists for proper bladder management in neuro-urology patients, the discordance between the two bodies, as well as, the overall lack of randomised controlled studies, results in problems with surveillance in this patient cohort. Other possible attributing factors to the low surveillance in the local population include the lack of patient registries and evidence-based literature.

In the Maltese NHS, the first step forwards towards better surveillance and hence the prevention of further complications in neuro-urology patients, has been the introduction and piloting of a “Bladder Management in Spinal Cord injury guideline”. However, much more work needs to be done in the field, both locally, through the introduction of specialised registries, as well as internationally, through good-quality randomised control studies.

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