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Lack of improvement after audit assessing the management of voiding dysfunction in patients with spinal cord injury: Necessity for institutional guidelines

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ABSTRACT

Introduction: Standard management guidelines for voiding dysfunction in patients with spinal cord injury (SCI) do not exist and these patients are managed on the basis of institutional protocols or individual judgment of managing physicians.

Objectives: To notice general trends and improvements over a five-year period, in the institutional practices related to management of voiding dysfunction in SCI patients.

Methodology: A retrospective cross-sectional study was conducted by Neurosurgery and Urology services together. A nine years (June 1995–June 2004) internal clinical audit of urological management of SCI patients was compared with a similar audit conducted five years later (January 2008–June 2010). Comparisons were made using chi-square test. A p -value of <0.05 was considered statistically significant. **Results:** A total of 146 patients were compared (89-pre-audit, 57-post-audit). The quality of documentation of examination findings worsened over the two study periods ($p = 0.002$). Although determination of baseline serum creatinine improved to statistically significant levels ($p = 0.019$), no imaging for the kidneys was performed as baseline in the post-audit period ($p = 0.000$). Similarly the number of urodynamic studies performed decreased from 11% to 1.75% ($p = 0.045$). The number of urological consultations, however, increased from 26% to 31.58% ($p = 0.452$). During follow-up, only 17 (19.1%) patients in the pre-audit study period and 6 (10.5%) in the post-audit study period were voiding spontaneously.

Conclusion: Our study of two eras clearly demonstrated a worsening trend in quality of patient management, which can be corrected by agreeing upon and implementing standard guidelines for management of SCI patients.

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1. Introduction

The annual incidence of Spinal Cord Injury (SCI) varies between 11.5 and 57.8 cases per million people in different countries.^{1–3} Studies from United States estimate that management costs per patient often exceed 1 million US dollars making SCI the second most expensive condition to treat and third amongst conditions requiring the longest length of stay in hospitals in the United States.^{4,5} Data regarding incidence of SCI in developing countries is lacking, although it has been suggested that where the incidence in

low socio-economic countries may be similar to the more developed countries, the frequency of complications, especially urological complications, may be much higher.^{6,7} Although urological complications are a leading cause of morbidity and mortality in patients with SCI,⁸ a consensus regarding the best treatment modality has not been reached yet.⁹

Clinical audits are an essential component of a health care system and are conducted on a regular basis to assess the performance and quality of care provided by an institution.^{10,11} Although indigenously developed management protocols exist, consensus on standard treatment guidelines for management of voiding dysfunction in patients with SCI is lacking and these patients are managed either on the basis of institutional protocols, or individual judgment of managing physicians.^{12–15} Clinical audit of these patients can help in identifying deficiencies in protocol and as

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a result aid in improving quality of care. However, these audits are seldom followed for any change in practice. The present study was conducted by Neurosurgery and Urology services together, to notice general trends and improvements over a five-year period, in the institutional practices related to management of voiding dysfunction in SCI patients after such a clinical audit.

2. Methodology

This study was done at the Aga Khan University Hospital (AKUH) Karachi. AKUH does not have a dedicated SCI service and SCI patients are admitted under Neurosurgery service, with urological management carried out by Urology service upon generation of a formal consult. The initial workup is done on admission and further workup is done during outpatient follow-ups by Urology service. The present study was conducted by the two services in an attempt to highlight flaws in management of SCI patients. This was a retrospective cross-sectional study based on two audits conducted five years apart. Medical records of SCI patients were reviewed first in 2005, for a nine years period (June 1995–June 2004). Patients admitted with SCI were identified using ICD-9 coding system and all adult patients (age ≥ 15 years) with voiding dysfunction were included. Data was collected using a proforma including the following variables: age, gender, time of presentation for evaluation, level of injury, type of spinal cord lesion, neurological examination findings, primary urological complaint, finding of urodynamic studies and present status of voiding on follow-up in clinics. Various deficiencies were identified during this review and verbal agreement was reached between Neurosurgery and Urology team members that urological consult will be generated for all SCI patients and they will be managed according to set guidelines; however, a formal, written protocol was not established at an institutional level. Nursing staff and case managers were also not involved. The next audit was conducted in 2010 to complete the initial audit loop. The same proforma was used for a similar group of inpatients, admitted from January 2008 to June 2010.

For both the audits, data was entered and analyzed using SPSS (Statistical Package for Social Sciences Chicago, Illinois version 16.0); descriptive statistics such as mean and standard deviation were calculated for continuous variables and proportion for categorical variables. Pre- and post-audit groups were compared using chi-square test. A p -value of <0.05 was considered statistically significant.

3. Results

A total of 146 patients were compared, with 89 and 57 from pre- and post-audit groups respectively (Table 1). Majority of the patients were male, with 69 (77.5%) and 51 (89.5%) in pre- and post-audit groups respectively. Most common level of SCI was thoracic (46%) prior to the audit, while most patients had cervical level SCI (47%) in post-audit study period. The quality of documentation of examination findings was found to have significantly worsened over the two study periods ($p = 0.002$). In terms of relevant laboratory and radiological workup, a mixed response was observed. Although the determination of baseline serum creatinine improved to statistically significant levels ($p = 0.019$) over the years, virtually no imaging for the kidneys was performed as baseline in the post-audit period ($p = 0.000$). Similarly the number of urodynamic studies performed decreased from 11% to 1.75% ($p = 0.045$) over the two study periods. The number of urological consultations, however, increased from 26% to 31.58% over the study period, although it was unable to attain statistical significance ($p = 0.452$). In terms of current voiding status, the follow-up status remained dismal with 37 (41.5%) and 26 (45.61%) patients lost to follow-up in the pre- and post-audit study period respectively. Of those that could be followed, only 17 (19.1%) patients in the pre-audit study period and 6 (10.5%) in the post-audit study period were voiding spontaneously whereas others were catheter or diaper dependent. There was no statistical difference observed in the current voiding status in the two study groups ($p = 0.186$).

4. Discussion

Urological complications have been one of the leading cause of morbidity and mortality in patients with SCI.⁸ These complications

include voiding dysfunction, urinary tract infections (UTIs), neuropathic pain, pressure ulcers, renal and bladder stones, sexual dysfunction, osteoporosis and depression.¹⁶ Management of these complications, especially voiding dysfunction without proper urodynamic evaluation can lead to numerous long-term complications.¹⁷ Therefore, appropriate investigations and bladder management is imperative for proper management of these patients.¹⁸

There are several available options for bladder management in these patients, however, in the absence of uniform guidelines or recommendations, the management of these patients remains inconsistent and varies greatly. There are numerous guidelines which have been proposed but a consensus regarding the optimum management of these patients has not been reached.^{12–14} The guidelines suggest that these patients should be managed in an SCI centre. The immediate management should include the use of an indwelling catheter which should be changed to clean intermittent self-catheterization on subsequent follow-up visits. The baseline investigations should include urine detailed report and culture, ultrasound of kidney and bladder, assessment of renal function (creatinine clearance), urodynamic studies, etc. Although, the basic management steps suggested in numerous protocols are similar, the long-term management, timing of

Table 1
Comparison of the pre- and post-audit study groups.

	Pre-audit $n = 89$ (%)	Post-audit $n = 57$ (%)	p -value
Age	15–80 years (Mean 35.10 years)	12–85 years (Mean 33.15 years)	
Gender	69M, 20F	51M, 6F	
Level of Injury			
Cervical	15 (16.85)	27 (47.36)	0.00
Thoracic	41 (46.06)	21 (36.84)	
Lumbar	25 (28.08)	9 (15.79)	
Sacral	8 (8.89)	0 (0)	
Examination: Anal tone			
Not Recorded	4 (4.6)	14 (24.56)	0.002
Decreased	76 (85.4)	39 (68.42)	
Increased/normal	9 (10)	4 (7.01)	
Laboratory workup: serum creatinine			
Yes	37 (41.5)	34 (59.65)	0.019
No	52 (58.5)	23 (40.35)	
Radiological workup: ultrasound kidney, ureter, bladder			
Yes	35 (39)	0	0.000
No	54 (61)	57 (100)	
Urology consult			
Yes	23 (26)	18 (31.58)	0.452
No	66 (74)	39 (68.42)	
CMG findings			
Hyper reflexia	9 (10)	1 (1.75)	0.045
Hypo reflexia	1 (1)	0	
Not done	79 (89)	56 (98.25)	
Management			
None	14 (27)	13 (22.8)	0.000
Foleys	48 (54)	39 (68.42)	
Suprapubic catheter	7 (8)	3 (5.26)	
Clean self-intermittent catheterization	10 (11)	2 (3.50)	
Follow-up			
Mean	7 months	8 months	
Yes	52 (58.5)	31 (54.39)	
No	37 (41.5)	26 (45.61)	
Current status			
Lost to follow-up	37 (41.5)	26 (45.61)	0.186
Spontaneous voiding	17 (19.1)	6 (10.5)	
Condom catheter	9 (10)	1 (1.75)	
Foleys catheter	7 (8)	9 (15.75)	
Suprapubic catheter	5 (5.5)	4 (7)	
Clean self-intermittent catheterization	7 (8)	5 (8.75)	
Diaper	4 (4.5)	1 (1.75)	
Expired	3 (3.4)	5 (8.75)	

repeating investigations and duration and frequency of follow-up has not been agreed upon. The latest Cochrane review also fails to effectively ascertain the optimal urological management of these patients, and therefore, even a dedicated multi-disciplinary approach towards prevention of complications in SCI patients has failed to influence health outcome.^{9,19} This issue has been highlighted previously by a questionnaire based study of 269 American urologists, who emphasized the need of a proper protocol for SCI patient management, including best follow-up investigations and frequency of follow-up.¹⁵

The present study highlights several interesting patterns. Although the frequency of seeking urological consults by Neurosurgery service improved with time, the overall clinical documentation, patient workup and definitive management declined. Even with improvements resulting from the first audit, only one-third of patients eventually received formal urological opinion. The possible reasons for the above findings are that after the results of the first audit, a verbal understanding was reached that these patients will be managed according to a set protocol; however, no formal implementation of protocol was carried out at an institutional level. Therefore, although a few consultants and residents did attempt to follow the protocol, mostly it was ignored. Being a service run by only three full time consultants, there was an increase in the number of urological consultations from neurosurgery side in the second audit, merely on the basis of the verbal directives. However the response from urology team, run by seven full time consultants and a larger patient load, was difficult to maintain in the absence of written protocols, and therefore inconsistent. Nursing staff and case managers were also not taken into confidence, an essential part of multidisciplinary team management approach.

The available literature suggests that all patients with SCI should undergo thorough urological evaluation including investigations like renal ultrasound, urine detailed report, urine cultures and urodynamic studies.¹⁸ Patients who undergo bladder management without urodynamic studies have been shown to develop a number of long-term complications.¹⁷ However, in our audits, only a few patients were found to have been subjected to any urological investigations and the least commonly performed investigation was in fact the urodynamic study. Moreover, the number of patients undergoing these investigations declined over the two audit periods, resulting in marked variation in patient care. It was felt that the available institutional protocols in developed countries are not entirely applicable in our clinical setting. Most of the patients cannot afford the cost of a long hospital stay, multiple investigations, routine clinic visits and rehabilitation. This clearly reflects the need to develop institutional specific management protocols. The different modalities used for voiding dysfunction include urethral catheterization, suprapubic catheter, clean intermittent catheterization and bladder augmentation.^{20,21} Various studies done to assess the safety of different modalities used for bladder management suggest that chronic urethral catheterization is associated with highest rates of urinary tract infection and other complications as compared to all other modalities.²² Despite these statistics, the most commonly used modality in our audits as well as in the literature from world over is long-term urethral catheterization, which in the two audit periods, actually increased.²¹ Suprapubic catheterization is also associated with long-term complications whereas clean self-intermittent catheterization is considered the safest method of management in patients with SCI.^{21–24} Our comparison was unable to identify any increase in number of patients on self-catheterization, thus still preventing the SCI patients from using the safest method of urinary drainage, but this could be explained by the increased number of cervical injury patients, as upper limb normal dexterity and movement is

necessary for self-catheterization, a major lacking in cervical injury patients.

The main limitations of the study are that both the pre- and post-audit were retrospective chart review and there was inconsistent documentation and work-up. A majority of the patients, in both the cohorts, were lost to follow-up so we may still be unsure of the way most patients are being managed. Cost and quality of life issues were also not addressed. Although, after the first audit, urological consults were generated for management of SCI patients, a standardized protocol for the management of these patients was not formulated.

The guidelines and protocols developed need to be practical, cost effective and suited for cultural limitations. Standard guidelines from North American and European system may not be entirely practical in our system. One way to overcome this would be to come with a draft of proposed guidelines, discuss it in local meetings, revise it appropriately, pilot it in a couple of centers, audit it for loopholes and again revise it accordingly, complete the audit loop and based on objective improvements, make it a standard. This will take time, effort and money. Our audit is the first step towards it. After the results of these two audits, a protocol has been developed (in Phase I) involving representatives from neurosurgery, urology and nursing teams. A consensus has been reached by all sectional representatives and costing has been done. The protocol also involves continuing education of residents and nursing staff, and awaits approval from ethical review committee and institution reviewers prior to pilot study and discussion at national level. Funding is also being sought to minimize expenditure and improve patient follow-ups.

5. Conclusion

The need of management and follow-up guidelines is imperative in urological management of SCI patients. Our study of two eras clearly demonstrated a decline in patient management, which can be overcome by implementation of standard guidelines developed through a consensus of both Urologists as well as Neurosurgeons. This includes consensus regarding proper timings and modalities of investigations, interventions as well as follow-ups.

Conflict of interest

None.

Source of funding

None.

Ethical approval

None.

Author contribution

Raza S, Shamim MS, Godil SS helped in the study design, preparation of questionnaire, analysis and writing of manuscript.

Biyabani R, Bari ME supervised both the audits and the manuscript writing.

Kumar R, Bhatti AA and Soomro S conducted both the audits and the analysis.

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