Asian Journal of Medicine and Biomedicine

Association between Severity of Benign Prostate Hyperplasia and Erectile Dysfunction in Two Largest Urology Centres in Pahang, Malaysia

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Abstract

Benign Prostate Hyperplasia (BPH) and Erectile Dysfunction (ED) are diseases that always bothering male > 40 years old. Both diseases are usually presented concurrently. Aim of the study is to determine association of BPH and ED, by measuring International Prostate Symptom Score (IPSS) and International Index of Erectile Function (IIEF-5) score. Uroflowmetry (Qmax), Prostate Specific Antigen (PSA) and prostate weight (PW) were be measured as well to look for the correlation with severity of BPH. A prospective study was conducted at 2 urology center in Pahang, Malaysia (Hospital Tengku Ampuan Afzan and Sultan Ahmad Shah Medical Center@IIUM), from 1st November 2022 until 30th of April 2023. Patient was assessed using IPSS and IIEF, as well as Qmax, PSA and prostate weight (PW). Total of 510 met the inclusion criteria and completed the study. The mean age group was 65.79 years old (65.23-66.35 years old). There were 68.2% Malay, 27.8 % Chinese, Indian 3.7 % and Orang Asli 0.2 %. Patient then labelled according to severity of Lower Urinary Tract Symptom (LUTS). Patient had IPSS score less than 8, it will be labelled as 'No LUTS' [18]. IPSS 8 and above will be labelled as 'LUTS' [18]. There were 271 patients or 53.1% of the subjects had 'LUTS', whereas there were 239 patients or 46.9% had 'No LUTS'. Patient had ED was categorized for patient who had IIEF-5 score less than 17 (<17). Patient with LUTS had ED 57.9%, whereas patient had no LUTS had ED was 42.1%. Pearson chi square calculated, p value <0.0001, which is statically significant. The prevalence of ED from the study was 78.6%. Prostate weight (PW) mean 52.17g with median of 51.0 g. The association between PW and LUTS is statistically significant, p value < 0.001. Prostate Specific Antigen (PSA) mean 3.43 ng/dl with median 2.6 ng/dl. The association between PSA and LUTS is not statically significant, p value 0.003. Qmax mean 12.14 ml/s with median 11.7 ml/s. The association between Qmax and LUTS is statically significant, p value <0.001. The study have shown statistically significant between association of LUTS and ED. Qmax and prostate weight have statistically significant correlation with presence of LUTS. However, from our study, there was no correlation of PSA reading and LUTS.

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Introduction

Benign prostatic hyperplasia (BPH) is a pathology, which is one of the causes for lower urinary tract symptoms (LUTS) in aging men [1]. Erectile dysfunction is defined as inability to attain and/or maintain an erection sufficient for satisfactory sexual intercourse [1]. Both conditions are common in adult more than 50 years old, and the prevalence was known to be increase with age [2].

As patient aging, LUTS/BPH as well as the erectile dysfunction symptoms are worsening [2]. LUTS consisted few components with standardized definition provided by International Continence Society (ICS) [3]. LUTS component in pathology process of BPH could be objectively measured with validated questionnaires known as International Prostate Symptoms Score (IPSS). These 7 questionnaires indicate severity of the disease. The score range from 0 to 35 and classified to 3 categories mild (0-7), moderate (8-19) and severe (20-35).

Erectile dysfunction is defined by ICS as complaint of inability to achieve and sustain an erection firm enough for satisfactory sexual performance [8]. According to Nordin et al (2019), the study conducted in Johor, reported prevalence of self-reported ED was 81.5 %, with severe ED was the highest, 29.5%.[9]. Malaysia among the highest prevalence of ED among South East Asia neighbors. In comparison to Thailand (29-65%) and Singapore (2-53%) [11]. As for ED, the severity is measured with validated score of International Index of Erectile Function (IIEF-5) [7]. The score range from 5 to 25 and classified to 5 categories severe (5-7), moderate (8-11), mild to moderate (12-16), mild (17-21), no ED (22-25).

According to the Cristiano Mendes Gomes et al 2020, presence of LUTS was associated with increased chance of ED in Brazilian men [4]. The most common condition for LUTS in male is BPH [5]. Slawomir et al 2012, study shown the impact of ED on patients with BPH was evident [6].

Both symptoms experienced by patients with BPH and ED were bothersome and may impair mental health, work productivity and health related quality of life [10]. Despite the modern era of medicine with multiple treatment and interventions, patients found it embarrassing to speak or discuss regarding sexual health, in particular ED. The young assume ED will resolved spontaneously, and the older patient accepting ED as part of aging process [12]. ED could be 'dipstick' in order to have general overview of patient health wellbeing, especially with co morbidities such as diabetes mellitus, hyperlipidemia, hypertension and others [13]

BPHED was a prospective, cross sectional study evaluating BPH and ED among men aged ≥40 years old in Kuantan, Pahang. The objective was to determine association of severity of BPH and ED. The outcome was to determine correlation between IPSS and IIEF-5, prevalence of ED and correlation between uroflowmetry (Qmax), prostate weight (PW), PSA with IPSS.

Materials and Methods

Study design and participants

It was a prospective cross sectional study. The study conducted from 1st of November 2022 until 30th of April 2023. The study included cases came to 2 largest urology center in Pahang, Malaysia. The center were Hospital Tengku Ampuan Afzan (HTAA) and Sultan Ahmad Shah Medical Center@IIUM (SASMEC@IIUM). Study participants were men more than 40 years old and less than 75 years old. A consent form was included in the questionnaire to inform the participants about study's aim and guarantee the confidentiality of their information and clinical findings.

Study participants were men ≥ 40 years old, who were referred to HTAA and SASMEC@IIUM.

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The study was approved by the local ethics committee, National Medical Research Register (NMRR) Malaysia and was performed in compliance with Good Clinical Practice and in accordance to Declaration of Helsinki.

Written consent was obtained from the participants prior to the study. The study was conducted in English and Bahasa Melayu.

Equipment and Materials
Assessment of BPH was based on International Prostate Symptom Score (IPSS) questionnaire comprising 7 questions on urinary symptoms and a score ranging between 0-35 points (0 = none, 1-7 = mild, 8-19 = moderate, 20-35 = severe) LUTS components of BPH assessed using a standardized protocol based on ICS definition [3]. IPSS questionnaires included. All terms and questionnaires were validated in English and Bahasa Melayu [14].

Definition of BPH classified severity of symptoms assessed with IPSS as being mild (0-7), moderate (8-19) or severe (20-35); size of prostate ≥ 20ml, and Qmax of 4 to 15 ml/s which indicative of Benign Prostatic Obstruction (BPO) [15].
For all the subjects involved, baseline uroflowmetry, prostate weight (PW), PSA were recorded and documented.

Severity of ED had been assessed using IIEF-5 questionnaires. IIEF-5 is a self-administered measure of ED that is cross culturally valid and psychometrically sound [7]. All the terms and questionnaires were validated in English and Bahasa Melayu [16]. Definition of ED was the total score of IIEF-5 questionnaires, is 25 or less. Mild ED 22-25; Mild- to-moderate ED 17-21; Moderate ED 11-16; Severe ED 1-10. For the purpose of this study the presence of ED was defined as a score <17 on the IIEF-5 [17].

Patient screened at the front counter during the visit, for eligibility to be recruited for the study.
Next, the patient provided with the information regarding the study, and consent was taken once patient fully understood and agreed to be the subject of the study.
After consent, patient has been asked to fill the demographic data, IPSS questionnaires and IIEF-5 questionnaires. Information regarding uroflowmetry, prostate weight (PW) and PSA level will be filled by the clinical research assistant.

Ethical approval
The study protocol had been reviewed and granted ethical approval by Medical Research and Ethics Committee (MREC) and International Islamic University Malaysia Research Ethics Committee (IREC). This study had been assigned with study protocol code by MREC (NMRR ID-22-01888-T86 (IIR)) and IREC (IIUM/413/013/14/11/2/IIR22-30).

Sampling and Sample Size Calculation
The sampling method that was used in this study was using Pocock's formula: $n = Z^2_{1-\alpha/2} \dfrac{(1-p)p}{\varepsilon^2}$

was used to calculate desired sample size as follows: $Z^2_{1-\alpha/2}$; reliability coefficient with α = 0.05, so $Z^2_{1-\alpha/2}$ = $(1.96)^2$; *p* = 0.815 based on ED prevalence of Rusli[9]; ε : relative error, ε = 0.05; therefore: *n* = 232.

The sample size was multiplied by design factor of 2, plus 10% reserved sample size. A total of 510 subjects were needed for the study. The prevalence rate of ED mentioned by Rusli [9] was 81.5 %. Thus, the use of *p* = 0.815.

Inclusion and Exclusion Criteria
The study's participants included male patient from Urology Clinic in HTAA and SASMEC@IIUM. Age limit for the patient to be included in the study was 40 to 75 years old. Inclusion criteria included Malaysian, able to give consent and able to understand English or Bahasa Melayu. Exclusion criteria included non

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Malaysian, less than 40 years old, more than 75 years old, active urinary tract infection (UTI), prostate carcinoma, mental disorders, neurological diseases and urethral strictures.

Statistical Analyses

The sample size calculation was performed on the primary objective and was determined to be 510 participants in total for both centers. Descriptive statistics were used to summarize continuous data. Categorical data were summarized as the number and the proportion of the total population. A Pearson chi-squared and Mann Whitney test were used for categorical and continuous variables, respectively, with an alpha level of significance of 0.001. The relationship between IPSS and IIEF was evaluated using Pearsons correlation coefficient and linear regression. Statistical analyses were performed with SPSS (version 20 for Windows).

Results

Total of 510 met the inclusion criteria and completed the study. The mean age group was 65.79 years old (65.23-66.35 years old). There were 68.2% Malay (n =348), 27.8 % Chinese (n=142), Indian 3.7 % (n=19) and Orang Asli 0.2 % (n=1).

Patient had IPSS score less than 8, it will be labelled as 'No LUTS' [18]. IPSS 8 and above will be labelled as 'LUTS' [18]. There were 271 patients or 53.1% of the subjects had 'LUTS', whereas there were 239 patients or 46.9% had 'No LUTS'.

Patient had ED was categorized for patient who had IIEF-5 score less than 17 (<17) [17]. Patient with LUTS had ED was 232 or 57.9%, whereas patient had no LUTS had ED was 169 or 42.1%. Pearson chi square calculated, p value <0.0001, which is statically significant.

The prevalence of ED from the study was 78.6% (n = 401).

Prostate weight (PW) mean 52.17g with median of 51.0 g. Interquartile range was 24. The association between PW and LUTS is statistically significant, (p value < 0.001).

Prostate Specific Antigen (PSA) mean 3.43 ng/dl with median 2.6 ng/dl. Interquartile range 2.0. The association between PSA and LUTS is not statically significant, (p value = 0.003).

Qmax mean 12.14 ml/s with median 11.7 ml/s. Interquartile range 4.8 ml/s. The association between Qmax and LUTS is statically significant, (p value <0.001).
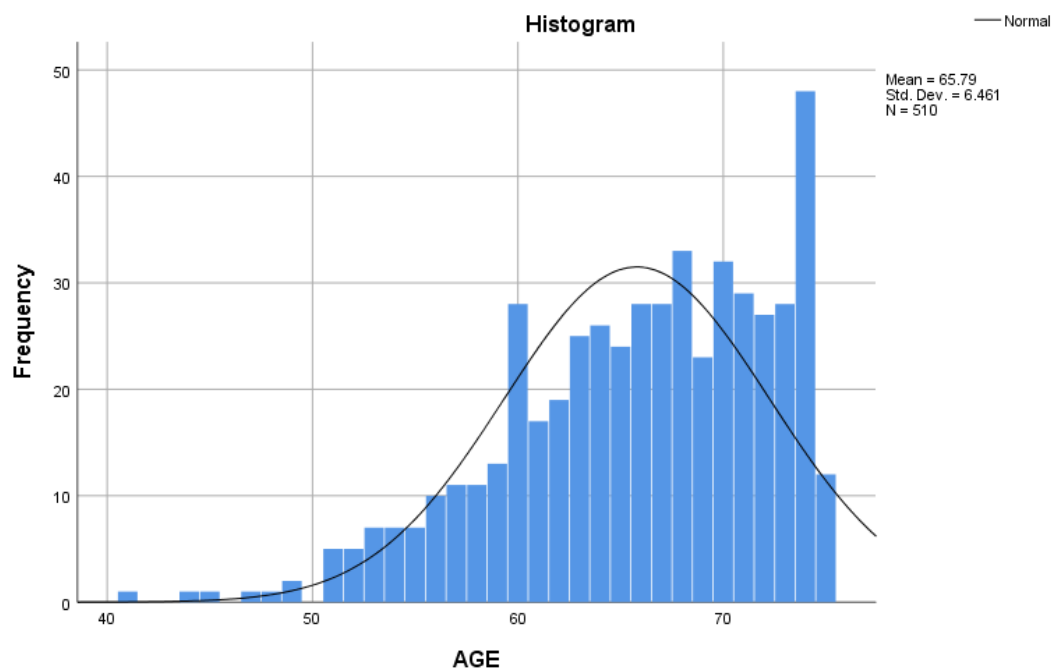
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Figure 1: The normal distribution of age. Mean age 65.79 years old

Table 1: ED and LUTS cross tabulation

			LUTS		Total
			NO LUTS	LUTS	
ED	NO ED	Count	70	39	109
		% within ED	64.2%	35.8%	100.0%
	ED	Count	169	232	401
		% within ED	42.1%	57.9%	100.0%
Total		Count	239	271	510
		% within ED	46.9%	53.1%	100.0%

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Chi-Square Test Output

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	16.772ᵃ	1	.000		
Continuity Correctionᵇ	15.898	1	.000		
Likelihood Ratio	16.869	1	.000		
Fisher's Exact Test				.000	.000
Linear-by-Linear Association	16.740	1	.000		
N of Valid Cases	510				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 51.08.

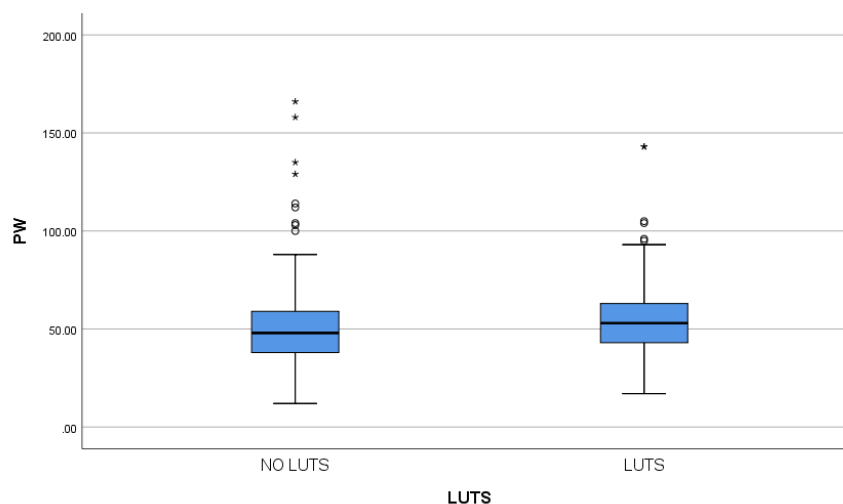Table 2: Pearson Chi square test used to analyse the data. p < 0.001

Figure 2: Boxplot of Prostate weight (PW) in g. Median for prostate weight for 'NO LUTS' was 48g and for 'LUTS' was 53g

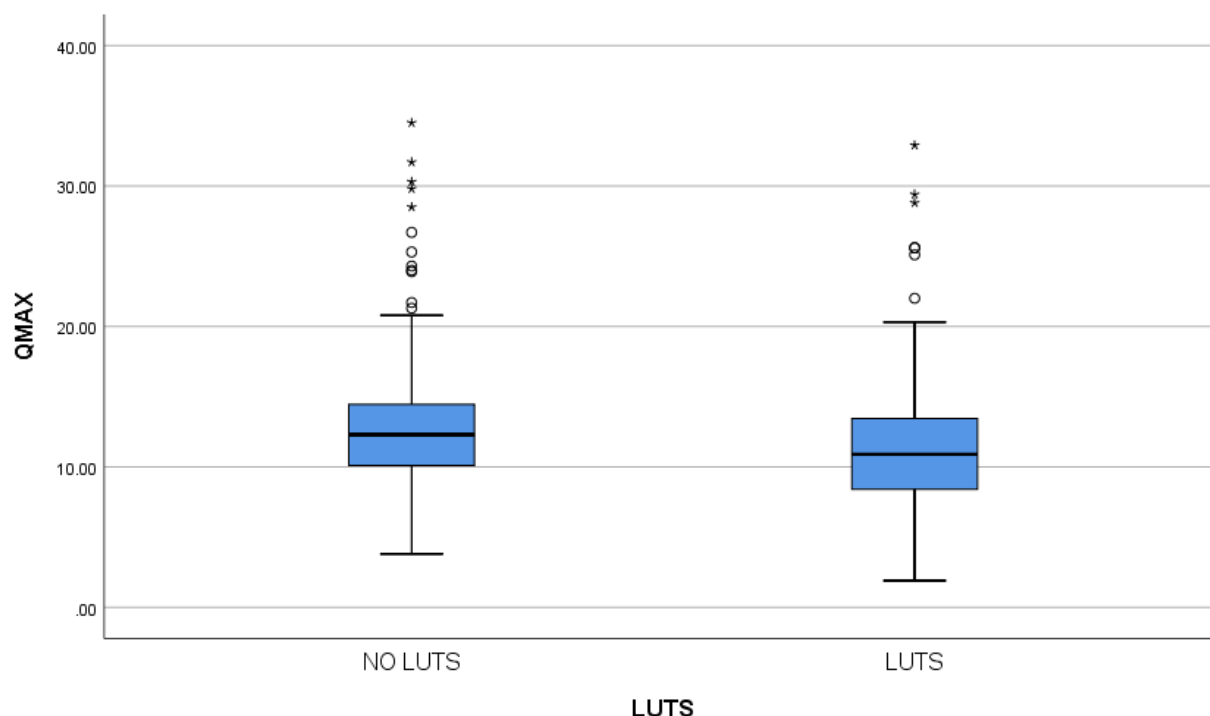Official Journal Faculty of Medicine, Universiti Sultan Zainal Abidin, Malaysia.

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Figure 3: Boxplot of Qmax in ml/s. Median for Qmax for 'NO LUTS' was 12.3ml/s and for 'LUTS' was 10.9 ml/s.

Discussion

This cross sectional study, performed at 2 urology largest center in Pahang, Malaysia. This was the first population based epidemiological study of BPH and ED in Malaysia. Patient who had at least 'LUTS' which means IPSS at least 8 and above (moderate and severe) was 53.1% of the participants [19]. Estimation from international studies according to ICS criteria to be around 45% (adults ≥20 years), 65% (adults aged ≥ 40 years) [19].

IPSS is used extensively worldwide for LUTS assessment. It is not exclusively on male participants only. Chapple et al [18], 39.8% and 43.2% of individuals aged 55-60 and 60 years respectively, who had IPSS ≥ 8. In Danish population, there was study conducted by Norby et al [20], LUTS prevalence 28% in men and 20% in women. Different questionnaires (IPSS and IIEF-5) been asked to participants. The response from the participants were different based on individual's interpretations and might result in inconsistencies between studies and translation into mother tongue or national language beside English, increase its variability. Even though IPSS was widely used, it was limited to 7 questionnaires, with limitation on storage component [17].

The association of LUTS and ED was proven by the study, as p < 0.001 in Pearson chi square. The result was similar to Wang et al [33]. The incidence of ED from the same study was 82.5%, which are comparable to our study, the prevalence was 78.6%. As the patient aging, the incidence for BPH and IIEF is increasing.

ED could be contributed by few etiologies such as chronic illnesses eg : Diabetes Mellitus, Hypertension, Cardiovascular disease [34]. The combination of hypertension, diabetes mellitus and hyperlipidemia may lead to formation of arteriosclerosis [35]. This will lead to cardiovascular event and increase the health care cost and burden to the nation and society.

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The study noted the prevalence of diabetes mellitus, hypertension, hyperlipidemia, chronic kidney disease and cardiovascular disease was 38.2 %, 75.5 %, 20.4 %, 52.2 % and 12.2 % respectively.

BPH and LUTS are common condition for elderly men. Eventhough, the condition was not life threatening, it may impaired the patient quality of life severely. In this study, the mean age was 65.79 years old with range of 40 to 75 years old. This is similar to 64.4 years old found in the study done by Badmus et al [22]. Other were similar findings were seen in [23][24]

The mean IPSS value in this study was 9.85. This is different from the study by Kennneth et al [25] and Ofoha et al [26]. This might be due to larger sample from this study in comparison to former 225 and 109 the latter respectively. Another reason could be the health accessibility is better in Malaysia compared to study mentioned which was in African continent.

The correlation of prostate volume and LUTS was found to be significant in this study (p <0.001). Similar findings was showed few other studies [26] [27]. There is also study showed there were no relations between LUTS and prostate weight [28].

Mean Prostate Specific Antigen (PSA) was 3.43 ng/dl, which not statically significant with LUTS (p = 0.03). This is similar to other study Tsukamoto et al [29] and Favilla et al [30]. In both studies, the sample study were 67 and 122 respectively have shown the correlation of LUTS and PSA reading was not statistically significant. On the contrary, study by Mochtar et al in 2003, had shown significant correlation between LUTS and PSA. This may be due to larger sample, which was n = 1859 [31].

Qmax mean 12.14 ml/s with median 11.7 ml/s. Interquartile range 4.8 ml/s. The association between Qmax and LUTS is statically significant, p value <0.001. This is similar to study by Oranusi et al [32], shown negative correlation between Qmax and LUTS but statically significant. The study also highlighted Qmax was the only parameter in uroflowmetry that statically significant.

Large sample was the main advantage of the study. Moreover the sample reflective of the social demography in Pahang, as well as Malaysia. Social demography in the study was Malay 68.2 %, Chinese 27.8 % and Indian 3.7 %. This can be compared with the national demography, which was Malay / Bumiputera was 69.6 %, Chinese 22.8 % and Indian 6.6 % [21].

As IPSS is objective tools in order to assess patient LUTS. However, it has some limitations, as it is based on patients' perspective. In correlation to the study, it imposed potential during data collection as patient had difficulty to objectify LUTS, despite study conducted in bilingual manner, English and Bahasa Melayu. Besides that, various background and level of education, from all walk of life may under report or over report their symptoms in IPSS. According to Putra [36], level of education has significant relationship and the ability to complete IPSS questionnaire. Visual Prostate Symptom Score could be useful adjunct in order to help patient to report their LUTS accurately, as patients were from various background and level of education.

IIEF-5 is simple, reliable validated tool for erectile dysfunction. However IIEF-5 score has some limitations. Tang et al [37] has described IIEF-5 score was unable to differentiate the etiologies of ED. Another parameter need to be considered is late onset hypogonadism (LOH). According to Wu et al [38], few components such as age, obesity, co-morbidities and smoking has showed significant reduction of total testosterone in aging men. Reduction in testosterone will resulted in low IIIEF-5 score [39].

Definition of health literacy according to World Health Organisation is cognitive and social skills which determine individual motivation and the ability to gain access to understand, and use information in ways

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to promote and maintain good health [40]. Health literacy among Malaysians are depending on various factors. The component of health literacy including decision making in 3 domains, health care, disease prevention and health promotion. According to Jaafar et al, the link between older age, lower formal educational level and lower income resulted in limited health literacy [41]. As far as the study concerned, mean age of the subjects was 65.79 years old. As patient aging, it impaired his physical and cognitive capabilities, hence reduced the health literacy among the subjects. As patient had limited health literacy, thus they will have the tendency to be diagnosed with non-communicable disease such as hypertension, diabetes mellitus and chronic kidney disease. These chronic diseases could impaired the erectile function, as well as IIEF-5 score [39]. The study noted the prevalence of diabetes mellitus, hypertension, hyperlipidemia, chronic kidney disease and cardiovascular disease was 38.2 %, 75.5 %, 20.4 %, 52.2 % and 12.2 % respectively. These findings could be confounding factors for the study.

Limitation of Study

This study was cross sectional study relying on questionnaires. Eventhough the questionnaires had been asked to patient in person, it relied on patient understanding, in order to comprehend the questionnaires and answer accurately. As the symptoms were tried to be scored using IPSS and IIEF-5 score, it always exposed to under-report or over-report which may potentially influencing affecting the study outcomes. Furthermore, the study ability to represent the broader population eg: Malaysia, might be limited as the data was gathered from single university hospital and state hospital.

Conclusion

The study have shown statically significant between association of LUTS and ED. Qmax and prostate weight as well have statically significant correlation with presence of LUTS. However, from our study, there was no correlation of PSA reading and LUTS.

Funding

Acknowledgements

Conflict of Interest Disclosure

None to declare.

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List of Abbreviations

BPH	Benign Prostatic Hyperplasia
ED	Erectile Dysfunction
HTAA	Hospital Tengku Ampuan Afzan
SASMEC@IIUM	Sultan Ahmad Shah Medical Center @ IIUM
IPSS	International Prostate Symptoms Score
IIEF	International Index of Erectile Function
ICS	International Continence Society
LUTS	Lower Urinary Tract Symptoms
PSA	Prostate Specific Antigen
PW	Prostate Weight
Q_{MAX}	Maximum Flow Rate
UTI	Urinary Tract Infection

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