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Health Related Quality of Life in Patients Post Prostatic Stenting for Benign Prostatic Hypertrophy

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Abstract:

Background:

Benign prostatic hypertrophy (BPH) is the most common benign tumor in men. 50% of men in the late fifth decade show prevalence increases to 90% by the ninth decade. Literature shows that prostatic stenting drastically reduces the symptoms of BPH. Since its efficacy in relieving symptoms of obstruction is so obvious, we wonder how this is reflected in patient's quality of life (QOL).

Objective:

Primary outcome measure:

To compare QOL using SF36v2 questionnaire between BPH patients on prostatic stent and patients who are urinary catheter dependent awaiting intervention.

Secondary Outcome Measure:

IPSS QOL score between 2 groups and correlate it with SF36v2 scores

Migration, encrustation, retention, infection and re-insertion rate in stented patients

Design, Setting & Participants:

Cross sectional review of the QOL in patients whom had underwent stenting of the prostate for BPH for 5 years from 2010. The patients were interviewed using the SF36 questionnaire. Two groups were interviewed, those that were on the urinary catheter awaiting intervention and those after the stent insertion.

Outcome measurements and statistical analysis:

Relationships with outcome analyzed using Fisher exact test, Independent t-test, correlation using spearman-rho test

Results and limitations:

The differences in QOL between the study groups were significant ($p<0.001$) while there were no correlations between IPSS and SF36 scoring systems. Encrustation, retention, infection and re-insertion rate were 12,12,16 and 8% respectively.

Limitations encountered are the retrospective analysis of one arm and the relatively small sample size.

Conclusions:

Stenting of BPH patients indeed improves the quality of life as evidenced by the significant difference between the groups.

Patient summary: *In this study we looked at outcomes form BPH in multietchnic societ. We found that prosthetic stenting drastically improves the QOL. We conclude that stenting is a significant method to treat BPH of all age and etnicity.*

1. INTRODUCTION & BACKGROUND

Benign prostatic hypertrophy (BPH) is the most common benign tumor in men. 50% of men in the late fifth decade demonstrate a pathologic evidence of BPH prevalence increases to 90% by the ninth decade[1] as this has been proven in autopsy studies increases to 90% by the ninth decade[1]. The symptoms associated with BPH have been classified as irritative and obstructive[2]. Transurethral resection of prostate (TURP) is a frequently performed urologic operation for the treatment of symptoms associated with BPH[3]. In current years, numerous other treatment modalities have been proposed as an alternate to TURP for treating BPH including prostatic stenting.

Scoring methods have been established to assist clinicians to evaluate the efficiency of interventions in the management of BPH. For instance, the International Prostate Symptom Score (IPSS) has been used to gauge the effects of medical treatments in BPH[4] and to evaluate urologic outcome after TURP and other interventions for BPH[5-10]. One limitation of these studies has been that the resulting data are disease-specific for urinary symptoms and do not gauge the effects of management on quality of life (QOL). Few studies to date have described the effect of TURP for BPH on QOL.

To test our hypothesis that prostatic stenting would improve the urologic symptoms and overall QOL in patients with BPH, we performed a cross-sectional, observational study.

A prostatic stent is a stent used to maintain open the male urethra and permit the passing of urine in instances of prostatic obstruction and lower urinary tract symptoms (LUTS). Prostatism is a common condition with a array of etiologies. Benign prostatic hyperplasia (BPH) is the most common cause.

There exist two categories of prostatic stent: temporary and permanent. Permanent stents are usually made of metal coils, which are inserted into the male urethra. The braided mesh is designed to expand outward, applying gentle constant pressure to hold open the part of urethra that obstruct the flow of urine. Permanent stents are used to relieve urinary obstructions resulting to benign prostatic hyperplasia, recurrent bulbar urethral stricture, or detrusor external sphincter dyssynergia.

In this study the Memokath Prostate 028 is used. The advantage of using this sort of intervention is that there is no risk of general anaesthesia to the patients. Its performed under local anaesthesia with minimal bleeding and the patient can be discharged the same day.

OBJECTIVE

Primary Outcome Measure:

To compare QOL using SF 36v2 Questionnaire between BPH patients on prostatic stent and patients who are CBD dependent awaiting intervention.

Secondary Outcome Measure:

To obtain IPSS QOL score between 2 groups and correlate it with SF 36v2 scores

Migration, encrustation, retention, infection and re-insertion rate in patients in patients on stent

2. MATERIAL AND METHODS

2.1. Study Design and Study Population

This study was a cross sectional review of the Quality of Life in patients whom had underwent stenting of the prostate for Benign Prostatic Hyperthrophy in National University Hospital of Malaysia (HUKM) from 1st January 2010 till 31st December 2015. The patients were interviewed using a validated questionnaire called the SF 36 either via phone or on the clinic appointment.

2.2. Procedure Technique

Prostatic stenting is performed under local anesthesia during cystoscopic examination of the urethra. It is commonly performed as a daycare procedure and therefore does not need admission to the ward. The stent is first placed in warm water to shrink the diameter down significantly. The stent in its not expanded form is inserted down the urethra using the cystoscope under direct vision. The aim of the stent is to alleviate the site of the prostatic urethra that is narrowed. As the medical practioner is satisfied with the site of placement, he will pass cold water down the scope and this expands the stents diameter. When it expands it pushes its walls against the inner part of the prostatic urethra and remains placed there. The patient is immediately relieved of the obstruction and is discharged from daycare within the hour. An appointment would be given to the patient to come to the clinic.

2.3. Patient Selection

Group A (Arm A) - Control

Inclusion Criteria:

All patients that were diagnosed with BPH on Foley's catheter awaiting a surgical intervention in HUKM and are able to give a verbal consent.

Exclusion Criteria:

Patients that were BPH but not requiring surgical intervention, those who refused and those on Foleys Catheter for reasons apart from BPH (Eg Stricture, Prostate cancer)

Group B (Patients On Stent)

Inclusion Criteria:

All patients that were diagnosed with BPH and had underwent prostatic stenting in HUKM from the 1st of January 2010 till 31st December 2016 and are able to give a verbal consent.

Exclusion Criteria

Patients that were diagnosed with BPH that were not stented or stented but for the reasons apart from BPH (Eg Stricture, Prostatic cancer).

2.4. Study Method

Patients that were previously stented for BPH and are still under the follow-up of the urology clinic in HUKM were identified form clinic and record office. Those who were still appearing for follow-ups were interviewed in clinic while those who were no longer visiting the clinic were interviewed via a phone call. These patient belonged to Group A. Another set of patients were interviewed in the clinic. These were patients that were diagnosed with BPH and have failed medical therapy and are on Foleys catheter awaiting a surgical intervention. These patients belonged to Group B.

Patients from both groups were interviewed using validated questionnaire SF 36 after they have read the patient information sheet and given a verbal consent. The questionnaire was available in 2 languages namely English and Bahasa Malaysia. 25 patients were collected from each arm totaling to a sample size of 50. The results were then placed thru licensed software specific for the calculation of the SF 36 QOL questionnaire.

2.5. Statistical Analysis

Questionnaires collected were placed thru a software to help calculate the scoring. This data was then entered onto a data collection form and then entered into the Microsoft Windows Excel database. Data analysis was undertaken using the Statistical Package for The Social Sciences (SPSS) version13.0. Chi-Square and Fisher Exact test were used for qualitative measures. Kaplan Meier Survival Analysis and Log Rank analysis were used for functional patency duration and comparison. Statistical significance was assumed when P value was less then or equal to 0.05

3. RESULTS

3.1. Descriptive Analysis

A total of 50 patients from Hospital University Kebangsaan Malaysia (HUKM) that fit the inclusion criteria outlined in Methodology section were recruited into this cross sectional with informed consent. The current study was done in accordance to the Universiti Kebangsaan Malaysia's Research Ethics Committee (REC) guidelines. Study population include patients who were diagnosed with BPH and stented, whereas the control group include BPH patients who were Foleys Cath.-dependent awaiting intervention. Since this is a retrospective study, data collection involved patients from year 2010 to 2015.

3.2. Demographic Characteristics of Study Participants

Table 1 shows the demographic data of study participants. Mean age for prostatic stent group (BPH participants on prostatic stent) was 78.4 (SD=7.9) years old, while for control group (CBD dependent awaiting intervention) it was 75.2 (SD=6.2) (Figure 4.1). Mean age for total respondents was 78.4 (SD=7.9) and the difference for age between the study groups was significant (p=0.003). Majority of the participants for control group was Chinese (64.0%), while in the stent group, there were equal number of Malay and Chinese participants (44.0% each). Nearly 40% (control group 36.0%, stent group 40.0%) of the study participants had no other illness.

As can be seen in Figure 2, majority of the study participants in total was Chinese (27 out of 50), followed by Malay (18 respondents) and the least was Indian participants, with only 5 of them in total. In the stent group, Malay and Chinese participants were equally

distributed (11 in each ethnic group), while in the control group, there were more Chinese participants (16 out of 50), followed by Malay respondents (7), and finally Indian (2).

Figures 3 shows the distribution of study participants according to illness status. In total, 19 out of 50 participants had no illnesses, while 7 were suffering from hypertension (HPT). Six participants each were IHD and DM while 5 were CVA participants. 4 participants were BA, 2 were COAD participants and finally 1 AF. The distribution of these participants in both the study groups was somewhat equal and similar pattern was observed when the chart was compared for both the groups.

3.3. Quality of Life (QOL) between the study groups, measured with SF36v2 PHS, SF36v2 MHS and IPSS

Table 2 shows the comparison of International Prostate Symptom Score (I-PSS) Quality of Life (QOL) and SF36v2 scores between the study groups. For the prostatic stent group, mean scores for SF36v2 PHS and SF36v2 MHS were 54.9 (SD=2.9) and 51.4 (SD=3.2) respectively. On the other hand, lower mean scores were observed in control groups for both SF36v2 PHS (35.9 (SD=3.3)) and SF36v2 MHS (30.6 (SD=4.7)), when compared to the prostatic stent group, and the differences between the study groups were significant ($p<0.001$). For the IPSS QOL, median was generated instead of mean because the data were skewed (not normally distributed). The medians for the prostatic stent and control groups were 6.0 (IQR= 2.0) and 3.0 (IQR=1.0) respectively, and the difference between the study groups was also significant ($p<0.001$).

Figures 4 and 5 show the comparison of mean SF36v2 PHS and MHS scores between study groups. The mean score for the prostatic stent group was higher than the control group (54.9 vs. 35.9) (Figure 4). Similarly, mean score for the prostatic stent group in SF36v2 MHS was also higher than the control group (51.4 vs. 30.6) (Figure 6). The median score for the prostatic stent group was also higher than the control group (6.0 vs. 3.0) when IPSS QOL was used instead of the SF36v2 (Figure 6).

3.4. Encrustation, retention, infection and re-insertion rate among prostatic-stented participants

Table 4 shows the encrustation, retention, infection and re-insertion rate in prostatic stent group. The encrustation and retention rates were 12% each, while 4 out 25 participants suffered from infection and 2 participants had to undergo re-insertion procedure (Figure 7).

Table1. *Demographic data of study participants*

Characteristics		**CBD dependent awaiting intervention**	**BPH participants on prostatic stent**	**Total**	***P***
Age[a]	Mean (SD)	75.2 (6.2)	81.7 (8.2)	78.4 (7.9)	0.003*
Ethnicity[b]	Malay	7 (28.0)	11 (44.0)	18 (36.0)	0.363
	Chinese	16 (64.0)	11 (44.0)	27 (54.0)	
	Indians	2 (8.0)	3 (12.0)	5 (10.0)	
Illness[b]	None	9 (36.0)	10 (40.0)	19 (38.0)	0.991
	HPT	4 (16.0)	3 (12.0)	7 (14.0)	
	IHD	4 (16.0)	2 (8.0)	6 (12.0)	
	DM	3 (12.0)	3 (12.0)	6 (12.0)	
	CVA	2 (8.0)	3 (12.0)	5 (10.0)	
	BA	2 (8.0)	2 (8.0)	4 (8.0)	
	COAD	1 (4.0)	1 (4.0)	2 (4.0)	
	AF	0 (0.0)	1 (4.0)	1 (2.	

				0)	

[a]Data were normally distributed and compared with Independent t-test

[b]Fisher's Exact Test

*significant at p<0.05

Table2. *Comparison of IPSS QOL and SF36v2 scores between study groups*

		CBD dependent awaiting intervention	BPH participants on prostatic stent	P
SF36 v2 PHS	Mean (SD)	35.9 (3.3)	54.9 (2.9)	<0.001 **
SF36 v2 MHS	Mean (SD)	30.6 (4.7)	51.4 (3.2)	<0.001 **
IPSS QOL	Median (IQR)	3.0 (1.0)	6.0 (2.0)	<0.001 **

Data were normally distributed and means were compared with Independent t-test

Data were not normally distributed and medians were compared with Mann Whitney U test

**significant at p<0.001

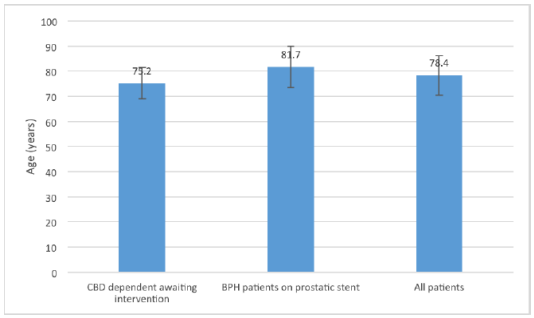

Figure1. *Mean age of participants*

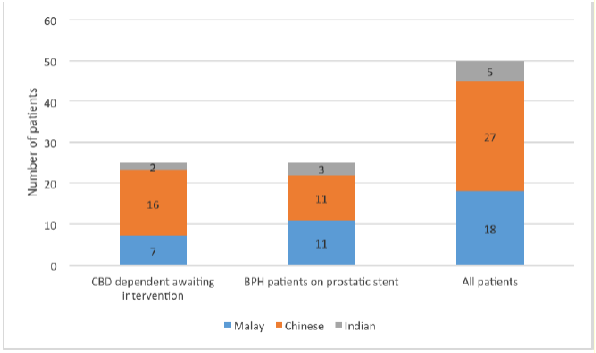

Figure2. *Distribution of study participants according to ethnicity*

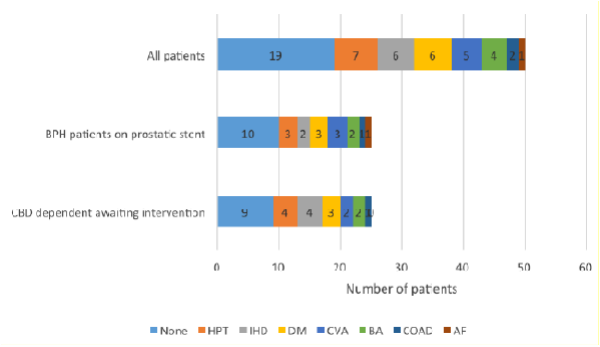

Figure3. *Distribution of study participants according to illness status*

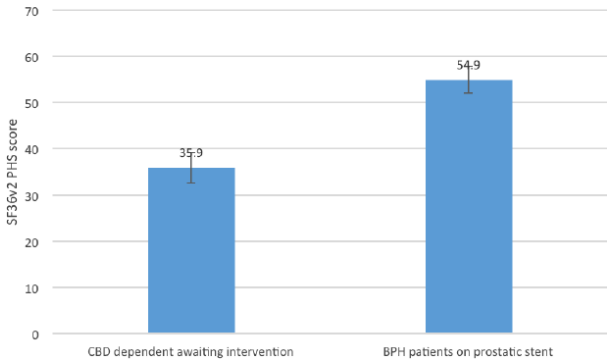

Figure4. *Comparison of mean SF36v2 PHS scores between study groups*

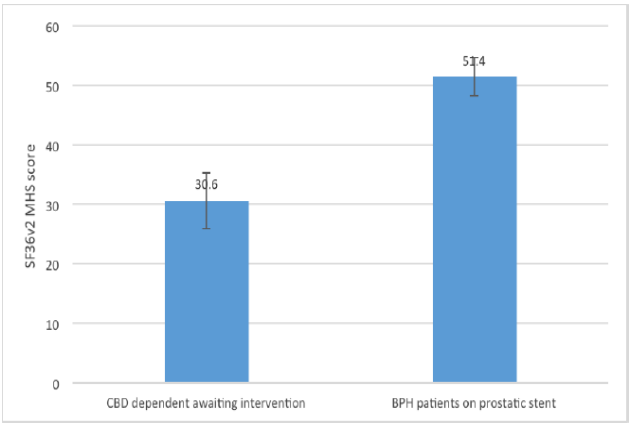

Figure5. *Comparison of mean SF36v2 MHS scores between study groups*

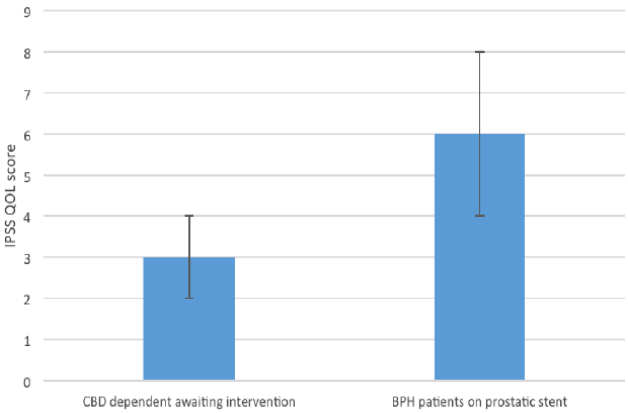

Figure6. *Comparison of median IPSS QOL scores between study groups*

Table3. *Correlation between IPSS QOL and SF36v2 scores*

Group			r^a	*P*
	IPSS QOL	SF36v2 PHS	-0.276	0.182
		SF36v2 MHS	0.042	0.842
	IPSS QOL	SF36v2 PHS	0.289	0.162
		SF36v2 MHS	-0.299	0.146

[a]Spearman-rho

Table4. *Encrustation, retention, infection and re-insertion rate in BPH participants on prostatic stent*

	n	%
Encrustation	3	12
Retention	3	12
Infection	4	16
Re-insertion	2	8

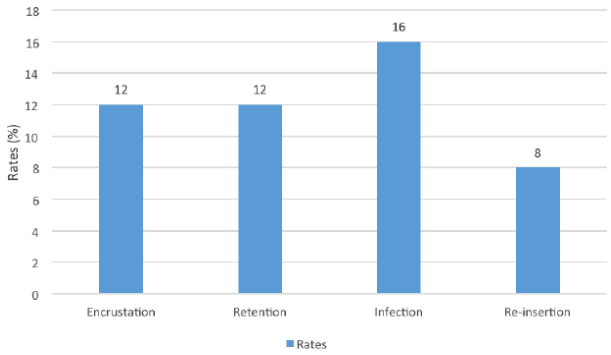

Figure7. *Encrustation, retention, infection and re-insertion rate in BPH participants on prostatic stent*

4. DISCUSSION

All the participants of this study are males, between the age of 62 till 100 years old and are of all 3 major races in Malaysia. The mean age for the prostatic stent group was 81.7 while the control group was 75.2. The age difference between the groups was large with the stented group oldest participant at 100 years old and the control group was 85 years old. We found this to be purely circumstantial. The overall mean age of patients in the study was 78.4. Majority of the participants in this study were of the Malay and Chinese race.

Since this is a pioneering paper in itself, there are no quality of life studies on the topic of prostatic stenting therefor the findings here would be a guide as well as set the standard for future stentings of the prostate in BPH. Nevertheless, various papers have been published for quality of life in transurethral resection of prostate (TURP).

The most important finding of this investigation was that the QOL of patients who underwent prostatic stenting for BPH had significantly improved after their procedure. The QOL assessment tool used in this study was selected to examine the overall condition of the patient (which includes a mental and physical health scale rather than using measures that are disease-specific (in this case, urinary symptoms as in IPSS).

Best practice in the future, will be defined for procedures such as prosthetic stenting, in terms of impact on QOL, rather than merely on technical accomplishment or peri-procedural complication rates[12].

Several previous, comprehensive prospective studies have addressed the effect of TURP on QOL. Emberton and associates[13] in a prospective cohort study of 5,276 men undergoing TURP, exhibited that the procedure was effective in decreasing the prostate related symptoms and also the disease specific QOL. Prostatic stenting is another procedure worth highlighting as it works well in BPH as well but QOL study has never been performed for one before.

Because QOL is an important component of true patient outcomes apart from just prostate related symptoms, this prompted our study to identify the QOL scores in prostatic stenting for patients of BPH.

The consideration currently focused to QOL as a vital outcome after operation is warranted and is likely to further intensify. In part, this relatively recent notice occurred because of the availability of validated, dependable tools (such as those utilized in this study). QOL analyses have resulted in identification of elements other than operative technique (eg, fatigue, preoperative pain, psychologic distress) on overall outcomes.

Our findings are consistent with other studies that have assessed QOL after TURP[14,15]. Fowler and associates[14] reported in 1988 that prostatectomy was successful in decreasing urologic symptoms in most patients and an enhancement in QOL but was not a validated QOL questionnaire.

Our study may suggest that improvements in QOL can be expected any months postoperatively, even in patients who are reasonably symptomatic, which has not been shown formerly. The importance of our work is that the enhancement in QOL scores we have demonstrated after stenting have not been used before to assess outcomes after stenting.

The current investigation was carried out retrospectively, and comorbidities that could have acted as confounding factors were included. Only previously validated and widely used QOL tools were used. Patients in this study were under the care of a single center, which ensured that procedural technique and peri-procedural care were uniform.

Although a small figure of patients was studied, we have established (using validated QOL tools) that TURP results in significantly greater QOL scores at 3 months. That this is clearly noticeable despite the limited power of our study serves to highlight the importance of the effect.

Our results should be translated in the light of several conceivable confounding factors. All of the patients in the control group were on urinary catheter, failed medical therapy and failed trial of void at least once.

No control group of patients who underwent TURP was studied because it was not our objective to evaluate TURP in comparison with stenting or against any of the other treatment options for BPH.

To date, most of the investigations on patients undergoing stenting for BPH have examined postoperative complications of the procedure. This study examined the influence of stenting on QOL. A consistent improvement in QOL was observed postoperatively after stenting in patients with BPH.

5. LIMITATIONS

Limitations encountered are the retrospective analysis of one arm and the relatively small sample size.

6. CONCLUSION

Based on the findings, it can be concluded that stenting in patients of benign prostatic hypertrophy does indeed improve the quality of life as evidenced by the significant difference between the groups. To the best of the authors' knowledge, this is the only quality of life study ever performed to assess the quality of life of patient after stenting for BPH. Therefore, based on this conclusion, we recommend prosthetic stenting be considered as another significant alternative to other modalities of treatment in managing BPH.

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