

## Analysis of short-term quality of life in post-surgical androgen deprivation therapy in advanced prostate cancer: a comparison of bilateral sub-capsular orchidectomy and bilateral total orchidectomy

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### ABSTRACT

**INTRODUCTION:** The use of Androgen Deprivation Therapy (ADT) in treating advanced prostate cancer poses a host of challenges that can affect the health-related quality of life (HRQoL) of these patients. Previous studies have demonstrated poor quality of life (QoL) of patients after ADT; however, there is a scarcity of the literature which compares HRQoL following bilateral subcapsular orchidectomy (BSCO) and bilateral total orchidectomy (BTO) in sub-Saharan Africa. This study aimed to compare the HRQoL of patients with advanced prostate cancer following treatment with BSCO and BTO.

**METHODS:** A randomized, single blind study concerning 64 patients with advanced prostate cancer; the subjects were randomized into BTO and BSCO treatment groups. The study was conducted over a period of ten months at a tertiary hospital situated in the North-central zone of Nigeria. Structured and validated instruments (FACT-PI and Karnofsky) were used to assess HRQoL during patient follow-up visits over a period of six months to obtain data regarding HRQoL and patient satisfaction. Statistical analysis using a chi-squared test and paired t-test were done to allow the comparison of HRQoL assessment scores and patients' satisfaction ratings between the two groups.

**RESULTS:** The mean age of the subjects were  $71.63 \pm 7.56$  years and  $70.06 \pm 8.79$  years for the BTO and BSCO group respectively ( $p = 0.449$ ).

Also, mean Gleason's score was 7.44 vs. 7.31 respectively ( $p = 0.714$ ). Health Related QoL assessment with FACT-PI and Karnofsky showed significantly better outcome after BSCO ( $p < 0.001$ ). Only 17% of the participants had psychological compromise after ADT.

**CONCLUSION:** The two techniques of orchidectomy differ significantly in their short term QoL response to treatment; BSCO was associated with better patient outcomes compared to BTO.

**Keywords:** Advanced Prostate Cancer, Androgen Deprivation Therapy, Subcapsular Orchidectomy, Total Orchidectomy, Quality of Life

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## INTRODUCTION

Prostate cancer is one of the leading causes of cancer-related death among men, largely because it is rarely diagnosed before the age of 50 [1]. Additionally, there are various factors that contribute to the lack of detection of prostate cancer including: The location of the prostate gland, the biological behavior of the tumor and the delicate nature of the treatment [2,4]. These challenges can affect the HRQoL, however are not limited to the patients; their spouses and relatives can also be affected [5–7].

Androgen deprivation therapy (ADT) remains the cornerstone of treatment in men with advanced disease [4,7]. While this stage of the tumor is associated with primary symptoms of bone pain, fatigue and decreased physical function, the elimination of testosterone further aggravates or in some cases can cause erectile dysfunction, vasomotor symptoms, osteoporosis, sarcopenia, psychological concern (depression) where they begin to feel ‘less of a man’ and anxiety caused by PSA hypervigilance [2,4,6–9].

In Africa, surgical castration is often utilized to achieve androgen deprivation in those with advanced prostate cancer due to its relatively lower cost compared to medical castration [10–13]. Surgical means of ADT can be achieved through bilateral total orchidectomy (BTO) which entails the removal of the entire testis, epididymis, and appendages or bilateral subcapsular orchidectomy (BSCO) which leaves behind the tunica albuginea and the epididymis. Both methods have been shown to have similar disease responses [14]. Comparison of BSCO and BTO as treatment methods has been conducted as hormonal ablation in patients with metastatic prostate cancer utilized biochemical variables on a long-term basis to demonstrate similarity in disease response and survival but the quality of life (QoL) assessment and comparison of the two methods were left as a subject for further research.

A number of cross-sectional studies have provided information about the effect of ADT on HRQoL [15] with an observation of poorer global QoL, worse physical function, less energy, poorer sexual function and an increasing number of hot flushes than those receiving other treatment modalities (including observation). However, the lack of literature regarding advanced prostate cancer patients of sub-Saharan African descent deserves

evaluation. Thus, the study aimed to compare the BSCO and BTO in the treatment of advanced prostate cancer among native Africans, with respect to clinical and psychological effects of ADT.

## METHODS

**Study Criteria:** A prospective, single-blind randomized comparative study among patients with advanced prostate cancer diagnosed at a tertiary health institution in the north-central zone of Nigeria. The study was carried out over a period of ten months (September 2016 and June 2017).

### Sample Size Estimation

Sample size estimation was determined with the formula;  $n = [A+B]2 \times 2 \times SD^2 / DIFF^2$ .

Where: n= the sample size required in each group; SD= standard deviation of primary outcome variable from the previous study; DIFF= size of difference of clinical importance; A= significance level and B= power.

From a previous local study by Magoha [16], who assessed subcapsular orchidectomy in the management of prostate cancer in Nigerians, the standard deviation of the primary outcome (SD) was 21, while size of difference of clinical importance (DIFF) was 14.6ng/dL at a power of 80% (0.84) and 5% significance level (1.96). Thus;  $n = [1.96+0.84]2 \times 2 \times 21^2 / 14.6^2 = 32.4$  approximately 32 patients and the total sample size for the study was (2n) 64 patients

**Inclusion Criteria:** Consenting patients with histopathological diagnosis of prostate adenocarcinoma with an advanced stage of the disease and choose surgical means of ADT as their primary mode of treatment.

**Exclusion Criteria:** Patients excluded were those who had other histopathological types of prostate cancer, patients on neoadjuvant hormonal therapy during the study period, patients with debilitating co-morbidities and patients with synchronous tumors.

**Patient selection:** Consecutive patients with advanced prostate cancer who met the inclusion criteria were recruited. Each patient was fully counseled on the two techniques of BSCO and BTO in the language best understood using the patient information sheet and informed consent obtained. Patient recruitment for the study was ended after attaining the estimated sample size.

**Patients Randomization:** The patients were randomized to either of the two trials designated

as A and B in equal numbers using block randomization to limit bias and achieve even distribution between the treatment arms.

Group A patients had BSCO while Group B patients had BTO. A block size of four was used because of the estimated sample size and the need to achieve an even balance between the groups. Each block contained an even number of four procedures equally distributed, but in a different order by random permutation. To further limit the bias and predictability which a single-blind study and small size block may cause, the blocks were chosen randomly to create an allocation sequence using the table of random numbers. The operative technique was declared before the surgical incision was made. Following completion of the procedures contained in a chosen block, another block was selected out of the possible six using the table of random numbers. This was repeated until the sample size was attained.

Ethical clearance was obtained from the hospital Ethical Review Committee (ERC) for a period of one year. Informed consent was obtained from all patients enrolled in the study. Patient refusal to participate or desire to withdraw participation at any stage of the study was respected without attempt at coercion or inducement. Strict confidentiality was adhered to in the management of patient records, results and details.

**Research instruments:** A structured interviewer-administered demographic and health questionnaire was used in collecting information on patients' demographics, histopathological diagnosis, Gleason's score of cancer and patient's satisfaction.

Also incorporated were the health performance status of the patients using Karnofsky performance status scale and a structured validated questionnaire: Functional Assessment of Cancer Therapy for Prostate cancer (FACT-PI version 4) [17] to assess each subject's QoL post- orchidectomy.

**Clinical outcome and quality of life assessment:** Clinical outcome and QoL were assessed in two perspectives- the physician assessment of health performance status using the Karnofsky performance status scale and the patient-reported outcome with the aid of Functional Assessment of Cancer Therapy for Prostate cancer instrument (FACT-PI). The Karnofsky performance status scale was administered by the physician on each subject pre-operatively and at 3rd month post-operatively. The scores were noted in the proforma.

The Functional Assessment of Cancer Therapy for

Prostate cancer (FACT-PI, version 4) questionnaire was administered to each patient pre-operatively and at six months post bilateral orchidectomy to assess the short-term quality-of-life index changes following the procedure. The scoring guide of this tool identifies those items that must be reversed before being added to obtain subscale totals. Negatively stated items were reversed by subtracting the response from "4". After reversing proper items, all subscale items were summed to a total, which represent the subscale score. The summation of all the subscale scores gives the Functional Assessment of Cancer Therapy for Prostate cancer total score (FACT-P total score), while the summation of the "physical and functional well-being subscale" and "prostate cancer subscale (PCS)" scores gives the Functional Assessment of Cancer Therapy for Prostate cancer Trial Outcome Index (FACT-P TOI) score. The Prostate Cancer Subscale score (PCS score) is the summation of items recorded under the "additional concern subscale." The higher the score recorded in these variables, the better the QoL of the patient [18,19].

The indices score calculated and compared in this study included: FACT-P total score, FACT-P TOI score and the PCS score. Score changes over the six months of follow-up were considered clinically meaningful when minimally important differences (MIDs) of 6 to 10, 5 to 9 and 2 to 3 were recorded for FACT-P total score, FACT-P TOI score, and PCS score respectively [18]. Comparison of the mean changes produced using these indices by the treatment arms was done with a view to establishing any significant difference in the clinical outcomes.

**Assessment of Patients' Satisfaction:** Numeric assessments of the patients' satisfaction with treatment was evaluated with an interval scale (percentages) in increasing order of satisfaction at the six-month follow-up. Aspects that were considered in the follow-up include the cosmetic appeal of the scrotum, the general perception of the procedure carried out and the psychological impact of the surgery. The appearance and feel of the scrotum were rated in comparison to the pre-operative state (100%), such that the closer the rating to this benchmark, the better the cosmetic appeal from the patients' perspective. Similarly, higher percentage ratings of the procedure were equated for better acceptance of the technique employed. A nominal scale (Yes/No) was used to determine the frequency of psychological

impairment (loss of their perceived ‘manliness’) in the patients.

**Data analysis:** The data obtained were entered into a computer spreadsheet and statistical analysis was done using Statistical Package for Social Science “IBM SPSS version 20.0.

Calculation of mean, range and standard deviation were done for variables with normal distribution while median and interquartile ranges were determined for non-parametric variables. The two groups were also compared based on age, the Gleason’s score, QoL assessment scores and patients’ satisfaction ratings using a Chi-square test. The results were displayed using tables, graphs and charts. For all statistical tests,  $p < 0.05$  was considered significant.

## RESULTS

The mean age of subjects was  $71.63 \pm 7.56$  years and  $70.06 \pm 8.79$  years for the BTO and BSCO group respectively ( $p = 0.449$ ). The Age peak incidence was in 70-79 year age group representing 45.3%. Sixty (93.8%) of the subjects were married, one patient (1.6%) was a divorcee and three patients (4.7%) were widowers.

The mean Gleason’s score ( $\pm$ SD) of all subjects was  $7.38 (\pm 1.35)$  with a range of 6 to 9. From the Gleason score, 50.0% were poorly differentiated ( $\geq 8$ ), 29.7% were moderately differentiated (7) and 20.3% were well-differentiated ( $\leq 6$ ). Also, the mean Gleason’s score was  $7.44 \pm 1.41$  vs.  $7.31 \pm 1.31$  in the BTO and BSCO group respectively ( $p = 0.714$ ).

**Table 1: Comparison of pre and post-operative quality of life within each treatment arm**

Variables	Group		D	t	p value
	Pre Op n=32	Post- Op n=32			
<b>QoL (using FACT-P total score)</b>					
<b>BTO</b>	95.29 $\pm$ 21.45	108.55 $\pm$ 23.99	13.25	-3.677	0.001*
Mean $\pm$ SD					
<b>BSCO</b>	95.15 $\pm$ 26.02	115.69 $\pm$ 20.07	20.54	-5.215	< 0.001*
Mean $\pm$ SD					
<b>QoL (using FACT-P TOI score)</b>					
<b>BTO</b>	54.93 $\pm$ 19.01	65.60 $\pm$ 19.73	10.67	-3.363	0.002*
Mean $\pm$ SD					
<b>BSCO</b>	55.22 $\pm$ 22.22	71.87 $\pm$ 16.09	16.65	-4.697	< 0.001*
Mean $\pm$ SD					
<b>QoL (using PCS score)</b>					
<b>BTO</b>	22.79 $\pm$ 8.81	27.26 $\pm$ 7.44	4.47	-2.845	0.008*
Mean $\pm$ SD					
<b>BSCO</b>	22.04 $\pm$ 9.84	29.28 $\pm$ 7.42	7.24	-4.035	< 0.001*
Mean $\pm$ SD					

FACT-P total score: Functional Assessment of Cancer Therapy for Prostate cancer total score; FACT-P TOI: Functional Assessment of Cancer Therapy for Prostate cancer Trial Outcome index, PCS: Prostate cancer subscale; BTO: Bilateral total orchidectomy; BSCO: Bilateral subcapsular orchidectomy; Pre-op: pre-operative; Post-op: post-operative; D: Mean difference; t: Paired sample t-test; \*: Statistically significant (i.e.  $p$  value < 0.05)

Using the Functional Assessment of Cancer Therapy for Prostate cancer Trial Outcome index score (FACT-P TOI score), a better post-operative QoL score was recorded in both groups at 6-month post intervention (Table 1). The mean positive difference was 10.67 and 16.65 for BTO and BSCO respectively. This change also exceeded the minimally important difference (MID) range of 5 to 9.

**Table 2: Changes according to domains of Functional Assessment of Cancer Therapy for Prostate Instrument (FACT-PI)**

Variable	Changes
	Mean $\pm$ SD
Additional Concern	5.85 $\pm$ 1.83
Physical Well Being	4.35 $\pm$ 0.85
Functional Well Being	3.46 $\pm$ 0.21
Emotional Well Being	2.57 $\pm$ 0.71
Social Well Being	0.66 $\pm$ 0.04

Both groups are comparable in age and Gleason's score respectively as there is no statistically significance difference in both groups.

The Karnofsky score of the subjects pre-operatively and at three months post-operatively showed a mean score of 69.06 and 81.56 respectively. A paired sample t-test showed the difference was statistically significant ( $p = <0.001$ ). Higher Functional Assessment of Cancer Therapy for Prostate cancer total score (FACT-P total score) was recorded by both groups of patients at six months, post bilateral orchidectomy (Table 1). The positive mean difference of 13.25 and 20.54 for BTO and BSCO groups respectively exceeded recommended minimally important difference (MID) range of 6 to 10.

Assessment of changes produced under the Prostate cancer subscale (PCS)-additional concern domain of Functional Assessment of Cancer Therapy for Prostate cancer instrument (FACT-PI)

revealed aggregate improvement in post-operative score and mean positive difference of 4.47 and 7.24 for BTO and BSCO groups respectively (Table 1) exceeding the recommended minimally important difference (MID) of 2 to 3. The greatest mean change or improvement was noticed in the additional concern subscale or PCS with a value of 5.85  $\pm$  1.83, followed by the physical well-being subscale and functional well-being. The least change over the 6 months of follow-up was in the social well-being domain (Table 2).

The comparison of the mean differences of FACT-P total score produced by each arm of treatment shows a statistically significant difference and a better outcome in the BSCO treatment arm (Table 3). Using the mean differences of the FACT-P TOI score for comparison between the groups, a statistically significant difference was noted with better outcome in the BSCO treatment (Table 3).

Evaluation of the cosmetic appeal and general perception of the surgery showed no statistically significant difference between the two groups. The average ratings (percentages in increasing order of satisfaction) are depicted below (Table 4). The overall perception of the procedures was very close at 75.3 $\pm$ 19.1% and 73.4 $\pm$ 22.2% ( $p=0.719$ ) for BSCO and BTO respectively. The result of the comparison of psychological impairment by nature of surgery revealed that 7 of BSCO patients (21.9%) felt compromised as against 4 of BTO patients (12.5%), but this difference was statistically not significant.

**Table 3: Comparison of change in Quality of life between bilateral orchidectomy (BTO) and bilateral subcapsular orchidectomy (BSCO)**

Variables	Treatment		D	t	p value
	BTO n=32	BSCO n=32			
<b>FACT-P total score Changes</b>					
Mean $\pm$ SD	13.25 $\pm$ 3.40	20.54 $\pm$ 4.50	7.291	7.312	< 0.001*
<b>FACT-P TOI Changes</b>					
Mean $\pm$ SD	10.68 $\pm$ 2.40	16.65 $\pm$ 3.90	5.975	7.381	< 0.001*
<b>PCS Changes</b>					
Mean $\pm$ SD	4.47 $\pm$ 1.22	7.24 $\pm$ 2.33	2.766	5.949	< 0.001*

FACT-P total score: Functional Assessment of Cancer Therapy for Prostate cancer total score; FACT-P TOI: Functional Assessment of Cancer Therapy for Prostate cancer Trial Outcome index; PCS: Prostate cancer subscale; Pre-op: pre-operative; Post-op: post-operative; D: Mean difference; t: Independent sample t-test; \*: Statistically significant (i.e.  $p$  value < 0.05)

Comparison of the average PCS score differences also produced a similar pattern with statistically significant difference and an outcome in favor of the BSCO group (Table 3).

**Table 4: Assessment and comparison of patients' satisfaction after orchidectomy**

Variable	Treatment		D/N	t/ $\chi^2$	p value
	BTO	BSCO			
	n=32	n=32			
<b>Appearance and Feel</b>					
Mean $\pm$ SD	58.2 $\pm$ 22.8	62.5 $\pm$ 23.9	-4.250	-0.728	0.469
<b>Overall Perception</b>					
Mean $\pm$ SD	73.4 $\pm$ 22.2	75.3 $\pm$ 19.1	-1.875	-0.362	0.719
<b>Feel Compromised</b>					
<b>Yes</b>	4 (12.5)	7 (21.9)	11 (17.2)		
<b>No</b>	28 (87.5)	25 (78.1)	53 (82.8)	0.988	0.320

BTO: Bilateral total orchidectomy; BSCO: Bilateral subcapsular orchidectomy t: Independent sample t-test;  $\chi^2$ : Chi square; D: Mean difference. Summation of the perception of impairment shows that 11 (17.2%) of the recruited patients were compromised by surgical castration.

## DISCUSSION

The two study groups were similar in terms of age and degree of differentiation of the adenocarcinoma being that there was no statistically significant difference between the mean age of patients recruited for the BTO and BSCO treatment groups (71.63  $\pm$  7.56 years vs. 70.06  $\pm$  8.79 years,  $p = 0.449$ ). The mean Gleason's score were 7.44 $\pm$ 1.41 vs. 7.31 $\pm$ 1.31 ( $p = 0.714$ ) for BTO and BSCO groups respectively. Hence, both treatment groups were well matched in their socio-demographic characteristics as well as in their tumor differentiation and distribution. Equally comparable was the distribution into treatment arms with equal numbers randomized into the groups giving a ratio of 1:1.

The clinical outcome of this study was approached from two perspectives i.e. the physician assessment using the Karnofsky performance status score and the patient-reported outcome with the aid of FACT-P instrument. It is worthy to note the majority of prostate cancer patients undergoing ADT will show varying magnitudes of positive clinical response [20]. In this study, an 18.1% improvement in the Karnofsky score rating (physician assessment) of all patients was observed at the third month after surgery. Further analysis of the treatment groups and subsequent comparison of pre- and post-operative mean values produced differences that were not statistically significant. Hence, neither BTO nor BSCO produced a better performance by the third month after the orchidectomy. However, comparison of the

mean pre and post-operative scores within each treatment arm showed that patients significantly fared better after three months with  $p$  values of  $<0.001$  in both groups. It can be inferred from the foregoing that in terms of clinical response (physician assessment) to orchidectomy, neither BSCO nor BTO showed a distinct advantage in the short term.

The goal of treatment for the patients in this study was palliative and this brings to fore the impact of the disease and its treatments on the patients' quality of life (QoL). Assessment of this impact using three derived scales of the Functional Assessment of Cancer Therapy for Prostate cancer Instrument (FACT-PI) showed that positive clinically meaningful changes (CMCs) were produced by the BTO and BSCO treatment arm. This was clear at the sixth-month follow-up when the mean differences were recorded for the Functional Assessment of Cancer Therapy for Prostate cancer total score (FACT-P total score, Functional Assessment of Cancer Therapy for Prostate cancer Trial Outcome Index score (FACT-P TOI score) and Prostate cancer subscale score (PCS score). These scores were shown to be positive and to exceed the recommended minimally important differences (MIDs) for these scales. This implies that both BTO and BSCO significantly improved quality of life of advanced prostate cancer patients by the sixth month of therapy.

Comparison of the changes produced after six months follow-up between the groups showed better patient-reported clinical outcomes with BSCO. In all scales used for comparison significant

p-value (<0.001) were recorded with the independent sample t-test. The implication is that while both techniques of orchidectomy produced improvement in QoL, the changes produced after BSCO were significantly better than BTO.

This better-reported outcome noticed with patients that underwent BSCO may be due to its perceived aesthetic superiority over BTO. This perception may affect the responses given to certain questions in the FACT-PI (general and specific domains) that borders on patients' satisfaction, acceptance of illness and manliness. Thus, higher scores from these questions may cumulatively have produced significantly better short-term quality of life changes in favour of BSCO.

In this study, the greatest changes were noticed in the PCS and physical well-being domain while the least occurred in the social wellbeing domain. This finding agrees with previous studies on health-related quality of life (HRQoL) in patients with advanced prostate cancer where such improvement was attributed to the reduction of 'pain' and increase in 'activity' [2,4]. The lowest change observed in the social-wellbeing subscale does not reflect the high pre- and post-operative values such that the difference was minimal after six months. These high values may be attributed to the close family network in African society.

The comparison of patients' perception of the cosmetic appeal of their scrotum after the surgery concerning what it was before orchidectomy as well as the extent of their satisfaction with the technique employed showed that patients that underwent BSCO rated the appearance and feel of their scrotum higher than their counterparts that had BTO. Similarly, their satisfaction with the procedure of orchidectomy was also better. This perception may be due to the residual "pseudotestis" (epididymis and tunica albuginea) left in the scrotum of those that had BSCO which may still mimic the "testicle". However, when the differences were subjected to an independent sample t-test, they were found to be insignificant on both counts. This implies that neither of the procedures confers a clear cosmetics advantage within six months of surgery. A previous study by Roosen et al [21] which compared BTO and BSCO found significantly better clinical outcomes with BSCO but the study considered post-operative complications without sufficient response obtained to enable evaluation of patient's

satisfaction and psychological bother. This study outcome, therefore, fills the gap in knowledge as 100% response was obtained from the research subjects.

The psychological consequence of loss of testicles was evaluated using a nominal scale and 17.2% of the subjects reported some impairment. The magnitude of this compromise was not quantified in this study due to the inability to access a standardized and validated questionnaire for this purpose. The outcome may therefore be viewed with caution. Worthy of note is the finding that seven of the eleven patients that reported psychological compromise belonged to the BSCO group. This result is at variance with the finding of Rud et al [22] who reported no psychological problems among 98 patients that had BSCO. However, the comparison of psychological compromise between the groups in this study was not significantly different, although a larger sample size may be needed to explore this difference.

The limited period of study (6 months) for this research precludes a longer duration of follow-up of patients to assess the long term changes in quality of life as well as survival pattern following orchidectomy.

## CONCLUSION

There was an improvement in the physician's assessment of performance status as well as a patient-reported clinical outcome following the two types of surgical ADT. Also, psychological morbidity was reported following surgical castration in the patients. In comparing the two procedures by outcomes, there was a similar clinical improvement after both methods of ADT but patients who underwent BSCO had a better short-term quality of life improvement.

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