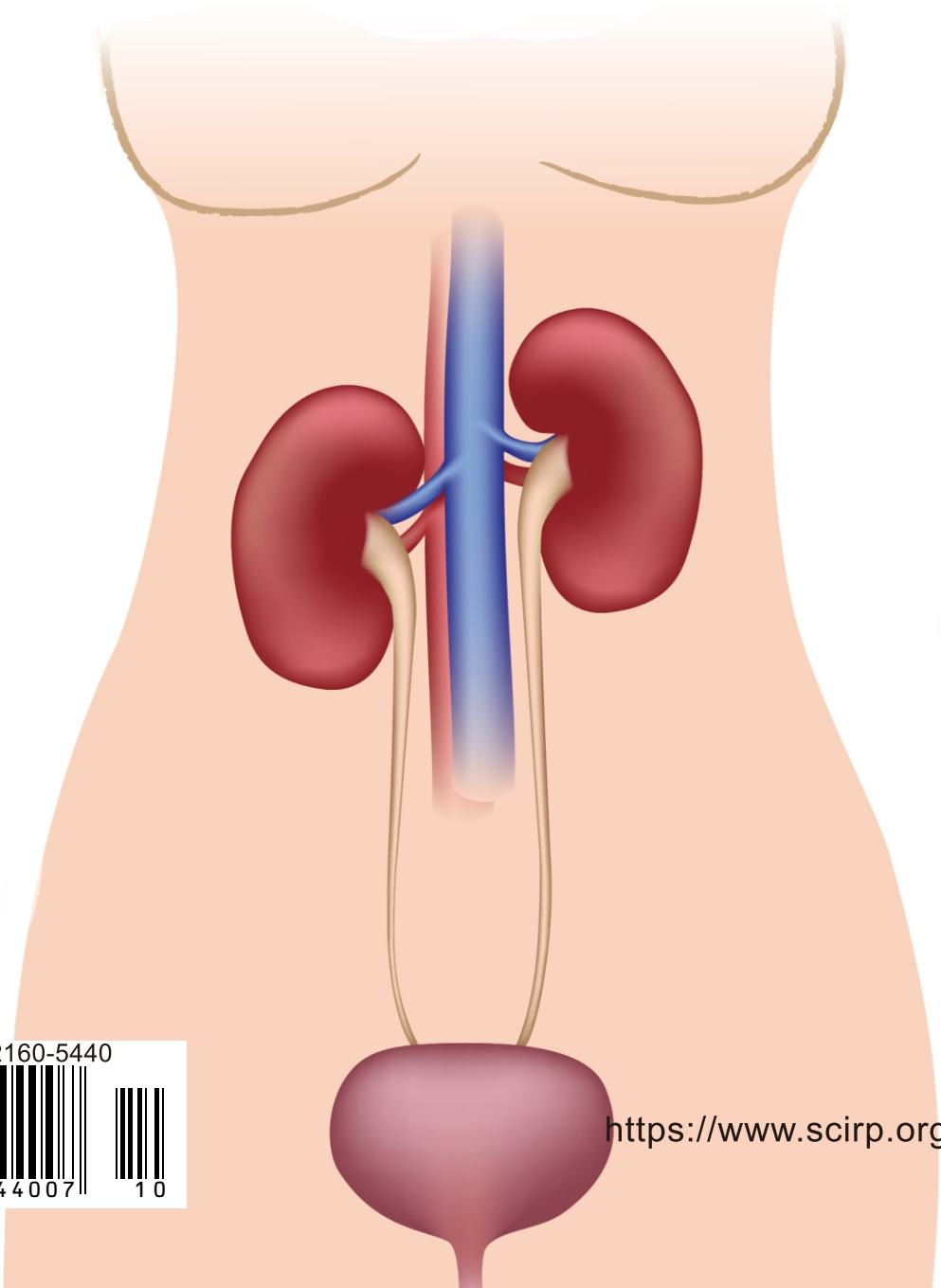


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Bladder Cancer: Epidemiological, Clinical and Histopathological Aspects at the University Hospital Point G, Mali

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Abstract

Introduction: Bladder cancer is a new tissue formation most often of urothelial origin with potential for local, locoregional and distant invasion. Among its risk factors, urinary bilharzia is endemic in our study area. The aim of our study was to present the epidemiological, clinical and histopathological aspects of bladder cancer in our department. **Patients and method:** This was a descriptive cross-sectional study over a 12-month period from January 1 to December 31, 2019. The study took place in the urology department of the university hospital Point "G". It included all patients hospitalized for bladder cancer. The epidemiological, clinical and histopathological characteristics have been sought and described. **Results:** A total of 74 patients were included in the study. Bladder cancer was the leading cause of cancer, accounting for 57.9% of all urological cancers. The mean age of the patients was 52.8 ± 16.25 years. A slight male predominance was observed with a sex-ratio of 1.2. Housewives were the most represented with 43.2% followed by farmers with 24.3%. Hematuria was the reason for consultation in 87.8% cases. The main risk factors found were urinary schistosomiasis (48.6%) and smoking (31.1%). These two factors were associated in 23.0% of cases. At diagnosis, 85.7% of patients were classified as T3 or T4 stage. Squamous cell carcinoma with 58.2% was the most common histological type followed by

urothelial carcinoma in 26.0% of cases. **Conclusion:** Bladder cancer is very common of cancer in hospitalized patients in our department. Diagnosis is more often made at an advanced stage. The most common histological type is squamous cell carcinoma.

Keywords

Bladder Cancer, Epidemiology, Clinic, Histopathology

1. Introduction

Bladder cancer is a new tissue formation most often of urothelial origin with potential for local, locoregional and distant invasion. It is most often a tumor invading the bladder muscle. It is sometimes a tumor which does not directly infiltrate the bladder muscle but given that it is of high histological grade, this could presage an evolution towards the mode infiltrating the bladder muscle. This ambiguity in evolution will lead us to speak more often of a bladder tumor. Bladder cancer with 16,390 deaths in 2016 is one of the deadliest genitourinary tumors in the USA [1]. In Europe, it is the second urological cancer after prostate cancer [2]. In Mali, it is the 4th most diagnosed cancer and is responsible for 4.0% of all cancer deaths [2]. Smoking and occupational exposure are the main risk factors [3]. In Africa, in bilharzia endemic areas, there is a histological type, squamous cell carcinoma, characterized by a high risk of local progression, recurrence and reduced sensitivity to chemotherapy and radiotherapy [4] [5]. This specificity requires the discovery of the tumor at an early stage for effective management, because no lifesaving therapy is effective in late stages. The low availability of endoscopic devices, especially in peripheral areas, the high cost of care compared to the income level of the most affected populations and the delay in consultation due to the similarity of signs between urinary schistosomiasis and bladder cancer, make it difficult to discover the pathology at the early stage. As a result, bladder cancer represents a real challenge for urologists working in bilharzia endemic areas of sub-Saharan African countries where it is characterized by a high specific mortality rate. Thus, with 5.2 deaths per 100,000 inhabitants, Mali is ranked 5th in the world for the highest age-standardized mortality rate of this condition [6]. The aim of our study was to present the epidemiological, clinical and histopathological aspects of bladder cancer in our department.

2. Patients and Method

This was a descriptive cross-sectional study over a 12-month period from January 1 to December 31, 2019. The study took place in the urology department of the Point "G" University Hospital, Mali. It included all hospitalized patients for bladder cancer. An investigation sheet comprising epidemiological data (age, sex, profession, level of education, risk factors), clinical data (consultation time, results of the physical examination, TNM 2009 classification) and histopatho-

logical data were recorded for each patient. All of this information was collected from the medical records of the patients. Data were analyzed using SPSS software.

3. Results

A total of 74 patients were included in the study. Bladder cancer with 10.6% represented the 4th reason for hospitalization after benign prostatic hyperplasia, urolithiasis and urogenital fistulas. However, it occupied the 1st rank of urological cancers with 57.9% ahead of prostate, cancer 26.5% and kidney cancer 14.8%. The mean age of the patients was 52.8 ± 16.2 years with ranges of 11 to 89 years. There was a slight male predominance with a sex ratio of 1.2. Housewives represented 43.2% of patients. The main risk factors found were urinary schistosomiasis, 48.6% and smoking, 31.1%. These two factors were associated in 23.0% of cases. The epidemiological aspects are summarized in **Table 1**.

Table 1. Epidemiological aspects.

Variables	Frequency	Percentage
Sex		
Man	40	54.1%
Woman	34	45.9%
Age (year)		
Less than 30	7	9.5%
30 - 50	22	29.7%
51 - 70	40	54.0%
Over 70	5	6.8%
Total	74	100
Profession		
Housewife	32	43.2%
Farmer	18	24.3%
Civil servant	11	14.9%
Other	13	17.6%
Total	74	100
Educational level		
Primary	19	25.7%
Secondary	5	6.7%
University	3	4.1%
Illiterate	47	63.5%
Total	74	100
Risk factors found		
Bilharzia	19	25.7
Tobacco	6	8.1
Bilharzia and Tobacco	17	23.0
None	32	43.2
Total	74	100

The consultation time was over 1 year in 59.4%. Hematuria was the main reason for consultation with 87.8% (n = 65). It was associated with lower urinary tract disorders in 55.4% (n = 41) of cases. Signs of advanced disease were found in 66.2% of cases, consisting of the pelvic shield, 36.5% and the hypogastric mass, 29.7%. At diagnosis, 85.4% of patients were classified as T3 or T4. Clinical aspects are presented in **Table 2**.

Urinary cytology was positive, revealing carcinoma in 63.0% of patients. The histological type obtained after biopsy during cystoscopy or after trans urethral resection of the bladder was dominated by squamous cell carcinoma which constituted 58.2% of cases. In **Figure 1** are illustrated the different histological types.

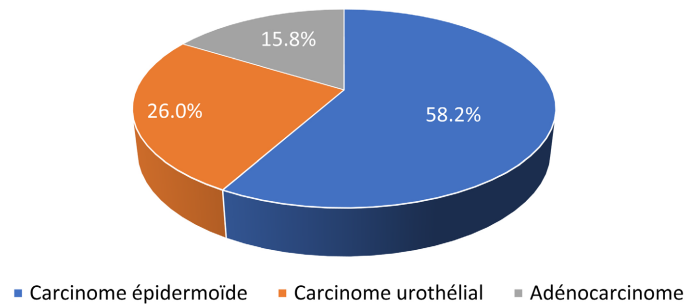


Figure 1. Histological types.

Table 2. Clinical aspects.

Variables	Frequency	Percentage
Consultation time (month)		
Less than 6	15	20.3
6 - 12	15	20.3
13 - 18	24	32.4
More than 18	20	27.0
Total	74	100
Result of physical examination		
Pelvic shielding	27	36.5
Hypogastric mass	22	29.7
Bladder globe	2	2.7
Normal	23	31.1
Total	74	100
Classification		
T2	11	14.86
T3	18	24.32
T4	45	60.82
Total	74	100

4. Discussion

Bladder cancer represented 10.6% of the activities of our hospitalization department. It was the most frequent urological cancer with 57.9%, ahead of prostate cancer, 26.5%. This finding is in contrast with other from countries in the same geographic area. Thus, in Benin, with a frequency of 28.5%, it came largely after prostate cancer, 69.0% [7]. In Senegal, the frequency of bladder cancer has fallen sharply compared to other urological tumors, dropping from 86.9% to 18.0% [8] where prostate cancer is predominant. This change in trend is believed to be due to an improvement in prostate cancer screening tools in recent years in the countries of Sub-Saharan Africa (SSA). In Mali, the high frequency of bladder cancer is more likely to be explained by a more severe endemic bilharzia (one in four people is affected) and more widespread with poor epidemiological control [9]. Both sexes were affected with almost the same prevalence in our study with a sex-ratio of 1.17. About 45.0% of the men were farmers, while 94.1% of the women were housewives. Men and women shared the same risk of exposure to bilharzia in rural areas. The slightly higher prevalence in men could be explained by other factors such as smoking. This phenomenon was until then quite marginal among women in Mali unlike the populations of countries in Europe and America.

The regions in which our patients most often come from were areas with high Bilharzia endemicity (Bamako, Koulikoro, Ségou and Kayes) due to the presence of numerous rivers and hydrological dams [10]. The populations there quite often practice fun aquatic activities, especially in childhood and or at work. Bladder tumors in Sub-Saharan Africa are most often related to a history of bilharzia infestation [11]. On average, a period of about 30 years separates the first bilharzial infestation and subsequent bladder cancer [12]. The first infestation occurring most often in childhood and would be responsible for the early onset of bladder cancer in bilharzia endemic areas, while in Europe and America, the age of onset is between sixth and seventh decade [1] [2]. In our study, urinary schistosomiasis was the risk factor most frequently associated with bladder cancer (48.7%). In 43.2% no factor was found, an old bilharzian involvement cannot be ruled out in these cases. Hematuria, which is the main sign sought to determine the history of urinary schistosomiasis, is only present in 50% of cases of *Shistosoma hematobium* [9].

Bilharzia was associated with 29.0% to 85.0% of squamous bladder cancers and 10% of transitional cell carcinomas in SSA [11]. Bilharzia and smoking both increase the risk of squamous cell cancer and urothelial bladder cancer [13], in our study this association was found in 23.0% of cases.

Our study revealed a great delay in consultation of patients suffering from bladder cancer. In 59.4% of cases, the consultation in a specialized environment was carried out more than 12 months after the onset of symptoms. This delay in consultation could be mainly due to the trivialization of hematuria in a context of endemic bilharzia. Thus in the majority of cases, 66.2%, the tumor was clinically evident in our patients by palpation of a hypogastric mass or the presence

of pelvic shielding on rectal examination. According to a study, 27.0% of squamous cell type bladder cancers consult at an inoperable stage in Africa [11]. In our study, 60.2% of tumors were diagnosed at the inoperable T4 stage, in agreement with the high mortality rate linked to bladder cancer recorded in Mali [6].

Confirming previous results in SSA [8] [11] [14], our study found a predominance of squamous cell carcinoma with 58.2% of cases, followed by urothelial carcinoma, 26.0%. *Shistosoma haematobium* infection was recognized in 1994 by the International Agency for Research on Cancer (IARC) and confirmed in 2012 as a class A carcinogen [15] [16]. In Egypt, a decrease in squamous cell forms in favor of urothelial forms with the decline of *Shistosoma haematobium* infection is evidence of the role of urinary schistosomiasis in the development of bladder squamous cell carcinoma [17] [18]. In Nigeria, depending on the study populations, the prevalence of squamous cell carcinoma ranges from 39% to 66% [11]. In Mali, in a region different from the site of our study, with high bilharzia endemicity where 73.5% of patients had a history of urinary schistosomiasis [19], the prevalence of squamous cell carcinoma was 82.1% [19]. This large difference between regions is mainly linked to the variation in the prevalence of urinary schistosomiasis.

Due to the late discovery of the pathology, only 14.86% of patients were able to benefit from a curative treatment. This treatment consisted of a total cystectomy with bladder replacement. For the rest of the patients, it was a palliative treatment consisting of transurethral resections of the bladder, urinary diversions, analgesics. Radiotherapy and chemotherapy were not part of our medical means because of the high cost for our patients on the one hand, the general condition of the patients sometimes very altered and the histological type often not very sensitive to radiotherapy and chemotherapy on the other hand.

This study poses two essential problems: Firstly, the delay in consultation due to the presence of the bilharzian endemic which leads to the appearance of histological type with little chemo and radio sensitivity and secondly the weakness of the technical platform by the unavailability and financial inaccessibility of therapeutic means for the moment poorly adapted to the histological type present. La résolution de ce paradoxe passe par la lutte contre la bilharziose qui permettra de diminuer le carcinome épidermoïde et de rendre accessible les moyens thérapeutiques pour les autres types histologiques en attendant l'inversion des proportions histologiques comme cela s'est vue en Egypte [17] [18].

The limitation of this study is that it is unicentric. Indeed, this center is a tertiary center that receives serious cases from other structures. This selection bias could explain the large proportion of terminal pathologies. A multicenter study could provide a more comprehensive picture of the bladder cancer situation in the country.

5. Conclusion

Bladder cancer is very common in patients hospitalized in our department. They are characterized by a delay in consultation responsible for a discovery of the

pathology at an advanced stage. Squamous cell carcinoma is the most frequent histological type, favored by endemic bilharzia, responsible for the delay in consultation by trivialization of hematuria. Effective control measures against urinary schistosomiasis should help reduce the prevalence of bladder cancer.

Conflicts of Interest

None.

Funding Source

None.

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Giant Angiomyolipoma Masquerading as Perinephric Abscess: A Diagnostic Conundrum

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Abstract

Renal angiomyolipomas are the most common benign tumours of the kidney accounting for up to 1% of all renal masses. Giant angiomyolipomas which have a size greater than 10 centimetres are rare entities with few cases reported in literature. Small angiomyolipomas are usually a symptomatic and increasing size correlates with symptomatology. These are usually incidentally detected or when symptomatic may present with an abdominal lump, flank pain or hemorrhage. Herein, we report a rare case of 45-year-old lady with giant angiomyolipoma with clinical presentation indistinguishable from perinephric abscess. The case is rare with regards to the large size of tumour and the discordant presentation unusual for an angiomyolipoma.

Keywords

Angiomyolipoma, Giant Angiomyolipoma, Perinephric Abscess

1. Introduction

Renal angiomyolipomas are the most common benign tumours of the kidney accounting for up to 1% of all renal masses. Giant angiomyolipomas which have a size greater than 10 centimetres are rare entities with few reported cases in literature. Small angiomyolipomas are usually asymptomatic and increasing size correlates with symptomatology. These are usually incidentally detected or when symptomatic may present with an abdominal lump, flank pain or hemorrhage. Here, we present a case that was misdiagnosed as perinephric abscess due to its peculiar presentation. The case is rare with regards to the large size of tumour and the discordant presentation unusual for angiomyolipoma.

2. Clinical Presentation

A 45-year-old lady presented to the emergency department with complaints of

fever, left flank pain and burning micturition for duration of one week. She had been on thyroxine 50 mcg for hypothyroidism for 8 years and was euthyroid. She had no other significant past medical or family history. Physical examination revealed pallor and a tender renal lump in left lumbar region. She had haemoglobin level of 8.4 g%, leukocyte count of 28,600/mm³, blood urea of 90 mg% and serum creatinine of 2.1 mg%. Urine routine microscopy showed 8 - 10 pus cells/hpf. Urine culture was sterile. Ultrasound of the abdomen showed a heterogeneously hypoechoic collection of dimensions 9.5 × 5.6 centimetres in left perinephric region visualised separately from the left kidney. An initial diagnosis of left perinephric abscess with acute kidney injury was made and management was instituted for the same. Patient was admitted for a course of IV antibiotics and therapeutic drainage of the abscess. Upon attempted diagnostic aspiration, only 5 millilitre of clotted blood was obtained. The initial diagnosis was called into question in this new light. Patient's kidney function improved with adequate hydration. A contrast enhanced computed tomography (CECT) scan was done for confirmation following normalisation of kidney function. CECT revealed giant left renal angiomyolipoma with large intra-tumoral bleed and an arterial feeder arising from left kidney (**Figure 1**).

Patient underwent selective arterial embolization which was unsuccessful. The patient was then planned for open exploration. Left simple nephrectomy was performed as nephron sparing nephrectomy was not deemed possible in this case due to large size of tumour encasing whole of the left kidney and intraoperative bleeding. The tumour measured 27 × 8.5 × 6 centimetres and weighed 2000 grams. On gross examination of cut section of the tumour specimen, a large area of intra-tumoral haemorrhage was identified (**Figure 2**).

Histopathology reiterated angiomyolipoma of the left kidney as the definitive diagnosis. Postoperative period was uneventful and patient was discharged on postoperative day 5 (**Figure 3**). Patient followed up in outpatient department for 6 months and was found to be doing well. Patient gave her full and informed consent for publication of case report.

3. Discussion

Angiomyolipoma (AML) is a tumour consisting of thick-walled poorly organised blood vessels, smooth muscle s and varying levels of mature adipose tissue [1]. Renal angiomyolipoma (AMLs) account for 1% of all renal masses [2] with overall incidence in general population of 0.07% - 0.3% [3]. Giant angiomyolipoma which have a size greater than 10 centimetres [4] are rare entities with few reported cases in literature of AMLs measuring greater than 20 centimetres.

Up to 80% AMLs are sporadic. The classical sporadic presentation is of a middle-aged lady, suggesting a hormonal component to tumour growth, with a single asymptomatic tumour as was in this case [5]. AML may occur with tuberous sclerosis complex (TSC) in 20% - 30% patients and approximately 50% of patients with TSC develop angiomyolipoma [6].

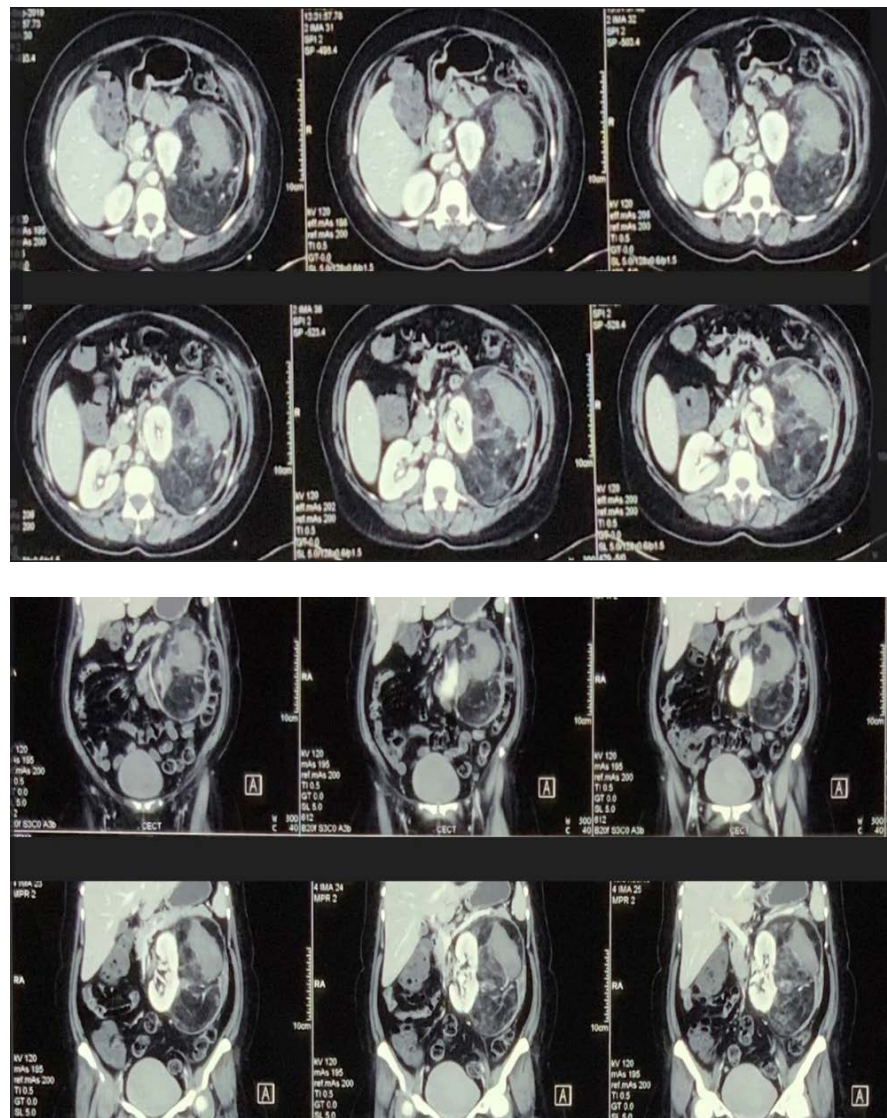


Figure 1. Axial and coronal views of contrast enhanced computed tomography showing large mass arising from left kidney laterally indenting its surface with negative 20 Hounsfield values (suggestive of fat) with a large area of hemorrhage within the tumour.

Asymptomatic tumours are usually less than 4 centimetres in size. Larger tumours tend towards symptomatic end of the spectrum which may include an abdominal mass, flank pain, haematuria, anaemia and haemorrhage. Life threatening intra-tumoral and retroperitoneal haemorrhage (Wunderlich syndrome) leading to shock may occur with large sized angiomyolipoma [7]. As seen in the presented case, wherein a giant angiomyolipoma presented with Wunderlich syndrome.

With the increased use of cross-sectional imaging over 80% of AMLs are now discovered incidentally, with haemorrhage at presentation (Wunderlich syndrome) seen in less than 15% and shock less than 10%. The classic triad of symptoms associated with renal masses of flank pain, palpable mass and haematuria were historically found in 37% - 41% of patients with AML [8].

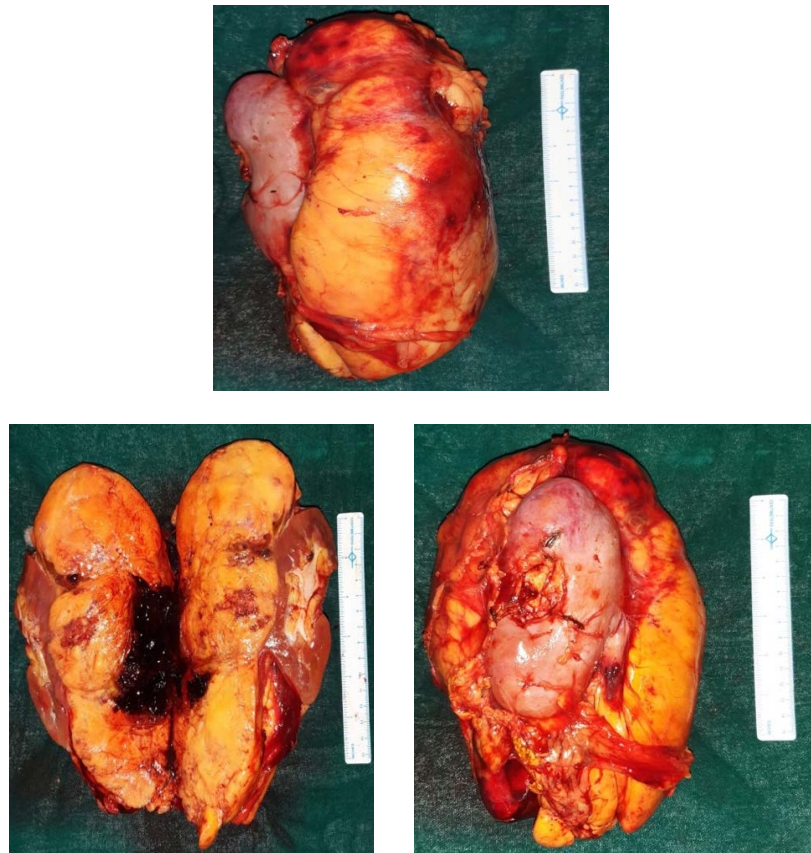


Figure 2. Left nephrectomy specimen showing giant angiomyolipoma arising from post-erolateral aspect of left kidney measuring $27 \times 8.5 \times 6$ centimetres, tumour is seen indenting the lateral surface. Cut-section through the kidney and tumour revealed a large area of intratumoural hemorrhage.

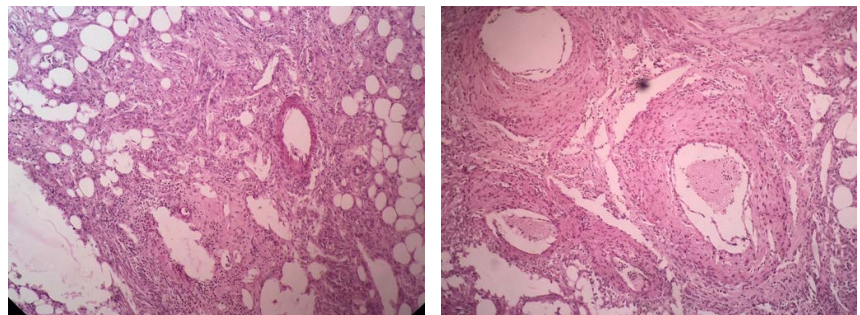


Figure 3. Histopathology sections demonstrating tumour composed of adipose tissue, thick walled blood vessels and smooth muscle. Vessel walls show prominent sclerosis.

Rare reports of angiomyolipoma mimicking renal cell carcinoma, Wilm's tumour and retroperitoneal liposarcoma are found in literature [9] [10] [11]. A few rare reports are present in which patients with ruptured angiomyolipomas presented with unexplained fever [12] [13]. In these cases, patients were known cases of bilateral angiomyolipomas with tuberous sclerosis and rupture of angiomyolipoma could be suspected. Angiomyolipoma mimicking a perinephric abscess as in our case report has not been reported in literature previously.

The diagnosis is usually apparent and definitive based on contrast enhanced computed tomography (CECT) scan with presence of fat in the lesion (confirmed by a value of -20 HU or less) being a diagnostic hallmark [14]. Possibility of a fat containing renal cell cancer (RCC), fat-poor angiomyolipoma and liposarcoma need to be considered and may warrant further evaluation using MR or percutaneous biopsy in doubtful cases [15]. MRI can be used to identify the fatty tissue. However, because the presence of bleeding in any renal tumour can mimic the typical pattern of angiomyolipoma, MRI should not be considered the diagnostic method of choice [4].

With regards to the present case report, the definitive diagnosis was established following CECT. The diagnosis of angiomyolipoma was missed on USG with haemorrhage within the tumour being misdiagnosed as perinephric abscess. CECT was deferred initially to correct acute kidney injury in the patient which was possibly due to hypovolemia associated with reduced intake.

Giant AMLs, as in our case, have been deemed to be at a higher risk of rupture due to formation of intralesional aneurysms with the size of intralesional aneurysms being a strong factor predictive of haemorrhage [8].

Treatment should be individualised depending on patient factors, tumour size and symptomatology. There is no one fits all modality with regards to angiomyolipomata management.

Small and asymptomatic tumours maybe managed conservatively with active surveillance. High risk of haemorrhage associated with large angiomyolipoma warrants intervention.

Conventionally, the criteria for intervention have been symptomatic lesions, size > 4 cm, suspicion for malignancy, women of childbearing age, an associated aneurysm size > 5 mm, concomitant TSC and poor access to follow up or emergency care as additional considerations for treatment [8].

Modalities may include partial or radical nephrectomy and/or selective embolization. Surgery in AML has progressed from initially recommended nephrectomy to nephron sparing surgery. This is especially important in AML associated with TSC as lesions are multifocal, bilateral and recurrent. Radiofrequency ablation is another modality which has shown some promise [8].

Newer modalities have emerged to the fore with enhanced and evolving understanding of molecular basis for angiomyolipomas. Mammalian target of rapamycin (mTOR) pathway inhibitors have emerged as a novel modality. There is a use for mTOR inhibitors in tuberous sclerosis patients with giant AMLs not amenable to other treatments or patients with less remaining renal reserve; however, questions as to the durability of responses, duration of treatment and impact of toxicity from chronic therapy remain. Additionally, the role of mTOR inhibitors in the management of patients with sporadic associated giant AMLs, as in the presented case, remains to be determined [8] [16] [17].

In our case, intervention following optimisation was warranted in view of the large sized tumour and evidence of haemorrhage. Selective angioembolisation was attempted preoperatively with the intention to minimise intraoperative

bleeding. However, embolization was unsuccessful. The patient underwent left simple nephrectomy.

Partial or nephron sparing nephrectomy and radio ablation could not be undertaken owing to the tumour encasing the whole kidney and intraoperative haemorrhage. There have been case reports of treating giant angiomyolipomas with nephron sparing surgery or excision of the tumour especially in cases of bilateral disease or solitary kidney in the settings of tuberous sclerosis [18]. Since there is further need to evaluate these approaches and our patient didn't have these special circumstances, we proceeded with the standard protocol.

4. Conclusion

To summarize, renal angiomyolipoma is a rare benign tumour mostly discovered as an incidental finding. The giant sized angiomyolipoma masquerading as perinephric abscess in our case report is a unique presentation, not reported previously. There is also established a need for further evaluation of other modalities of treatment in sporadic cases of giant AML with better outcomes and maximal organ preservation.

Acknowledgements

None.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Presentation and Management of Wilm's Tumour in Sudan (Three Centre Experience from 2014-2016)

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Abstract

Background: Wilm's tumour is a cancer of the kidneys that typically occurs in children younger than fifteen years of age and rarely in adults. With an early diagnosis and proper management of Wilm's tumour by Multi-modal approach, excellent outcome can be obtained. This study was designed to reflect the clinical presentations and focus on different management modalities with an outcome of Wilm's tumour in Sudan. **Patients and methods:** This descriptive, retro-prospective analytic study included all patients of Wilm's tumour at Soba University Hospital, Gezira national paediatric surgery centre and Khartoum teaching Hospital from January 2014 to January 2016. **Results:** Thirty patients (pts) were included. Females were predominant in a ratio of 3: 1 to males. The mean age was 3.0 - 5.9 years. Those who came from central and western of Sudan were more affected. Most patients presented with abdominal mass 28 pts (93.3%), followed by abdominal distension in 16 pts (53.3%), while the less frequent presentation was haematuria seen only in 2 pts (6.7%). The multimodal approach: surgery and chemotherapy used in 21 pts (70%) and single modality was used in nine patients: surgery alone in 6 pts (20%), or chemotherapy alone in 3 pts (10%). The patients discharged uneventfully 23 pts (76%). Morbidity was seen in two patients. Deaths were occurred in five patients in the study (16.7%). **Conclusion:** The finding of this study reflected that Wilm's tumour has an excellent outcome when patient was managed by multimodal approach.

Keywords

Wilm's Tumour, Multi-Modal Approach, Nephrectomy, Chemotherapy, Outcome

1. Introduction

Wilm's tumour is a malignant tumour originating in the cells of the kidney and one of the common renal tumour that primarily affects children and rare adult [1], and also known as nephroblastoma. Wilm's tumour may arise in either or both kidneys. The condition is named after DR. Max Wilm's, the German surgeon in 19th century (1867-1918) who first described it [2]. He is recognized that the cancer develops from immature kidney cells. It is made up of cells that are significantly immature and abnormal. These cells are also capable of invading nearby structures within the kidney and travelling out of the kidney into other structures. Malignant cells can even travel through the body to invade other organ systems, most commonly the lungs and brain. These features of Wilm's tumour make it a type of cancer that, without treatment, would eventually cause death. However, advances in medicine during the last 20 years have made Wilm's tumour a very treatable form of cancer [3] [4]. Treatment is a living example of success achieved through a multidisciplinary collaboration of the National Wilm's Tumour Study Group (NWTSG) and the Societe Internationaled Oncologie Pediatrique (SIOP) [5] [6].

Pathogenesis of Wilm's tumor: Most cases of Wilms tumor are not caused by inherited genetic factors and do not cluster in families. Approximately 90 percent of these cancers are due to somatic mutations, which means that the mutations are acquired during a person's lifetime and are present only in the tumor cells. Mutations that are present in cells throughout the body (called germline mutations) are responsible for the remaining 10 percent of Wilms tumor cases and cause either Wilms tumor without any other signs or symptoms or syndromes in which Wilms tumor is one of multiple features. These cases follow autosomal dominant inheritance, which means one copy of the altered gene in each cell can cause a Wilms tumor-related syndrome or increase a person's chance of developing the cancer alone. Most of these cases result from new (de novo) mutations in the gene that occur during the formation of reproductive cells (eggs or sperm) or in early embryonic development. The AMER1 gene is located on the X chromosome (one of the two sex chromosomes), so when Wilms tumor is caused by mutations in this gene, the condition follows an X-linked dominant pattern. In females (who have two X chromosomes), a mutation in one of the two copies of the gene in each cell is sufficient to increase a person's chance of developing cancer. In males (who have only one X chromosome), a mutation in the only copy of the gene in each cell increases their cancer risk. In many cases, the genetic basis for Wilms tumor and the mechanism of

inheritance are unclear [7].

2. Patients and Methods

This study was conducted in Khartoum Teaching Hospital (KTH), Soba University Hospital (SUH), Gezira National centre of paediatric surgery (GNCP) in Sudan in two years' period from January 2014-January 2016. All patients in these centres were diagnosed with Wilm's tumour included. Total of thirty patients met the criterion of inclusion were studied for different clinical presentations, focusing on management modalities, duration of hospital stayed and outcome observed up to seven months.

3. Results

A total of 30 patients with Wilm's tumour, who satisfied the inclusion criteria were studied. There is female predominant 18 pts (60%) while male 12 (40%), with male to female ratio of 1:3. Most of the patients 11 (36.7%) were in the age group 3.0 - 5.9 years, whereas those more than 6 years were only 5 pts (16.7%) and patients of less than one-year age were only 6 pts (20%). Most of the patients were from either Central or Western part of Sudan 14 pts (46.7%) and 10 pts (33.3%) respectively, four patients came from East (13.3%) and only two patient from north of Sudan (6.7%). Most of the patients presented by abdominal mass 28 (93.3%) patients and some of them associated with abdominal distension in 16 (53.3%) patients. While the less frequent symptoms over all is blood in urine seen only in 2 pts (6.7%) (**Table 1**). Twenty-two patients (73.3%) presented in five weeks or less However 6 (20%) of patients presented after the 10th week. The commonest clinical sign was abdominal mass seen in almost 29 pts (96.7%), followed by anaemia in 8 pts (26.7%), while less frequent was haematuria seen in 3 pts (10%), organomegaly in 4 patients (13.3%) and hypertension in 1 patient (3.3%).

The investigations modalities needed to confirm the diagnosis and determine the extent and effect of the disease. Radiological investigations (Computed tomography scan and abdominal ultrasounds scan) were done in 93.3% and 73.3%

Table 1. Presenting symptoms of patients with Wilm's tumour in the study.

Symptoms	Frequency	Percent
Abdominal mass	28	93.3
Abdominal pain	07	23.3
Abdominal distension	16	53.3
Fever	09	30.0
Nausea	04	13.3
Vomiting	06	20.0
Anorexia	07	23.3
Blood in the urine	02	6.7

respectively, laboratory investigations were done also (60% - 97%), and confirmatory tissue biopsy: true cut needle biopsy (TCNB), excisional biopsy and incisional biopsy in 60%. There are multi-modal protocols for treatment of Wilm's tumour in the study. In Soba Hospital the protocol of treatment is preoperative chemotherapy followed by surgery (nephrectomy), while Khartoum Teaching Hospital and Gezira National Centre of Paediatric Surgery treated their patients by surgically (nephrectomy) first followed by postoperative chemotherapy. In the study multi-modal approach surgery (nephrectomy) and chemotherapy used in 21 pts (70%), while single modality was used in 9 patients: surgery (nephrectomy) alone in 6 pts (20%) and chemotherapy alone in 3 pts (10%). The mean duration of hospital stay was 4.0 ± 4.2 week (range 1 - 15 weeks). Most of patients 22 pts (73.3%) discharged within five weeks. Wilm's tumour patients who stayed in hospital four more than 10th week only 2 pts (6.7%). The majority of patients were discharged uneventfully 23 pts (76%). Morbidity was seen in two patients one of chronic renal failure and other with intraabdominal haemorrhage. Deaths were occurred in five patients in the study (16.7%). The outcome was good in patients presented earlier. Patients presented in five weeks or less, had uneventful discharge in 18/22 (81.8%) and 13.6% mortality rate, whereas those presented eleven weeks or more, had uneventful discharge in 3/6 (50%) and 33.3% mortality rate, but the difference is not statistically significant, p value 0.492 (**Table 2**). Twenty-one patients had multimodal treatment (surgery and chemotherapy) 18 (85.7%) were discharged uneventfully, morbidity in 1 (4.8%) and there were two mortalities (9.5%). Six patients underwent surgery (nephrectomy) alone: one third of them died 2 pts (6%). Three patients had received chemotherapy alone: one was discharge in good condition, one developed complication and the third case died. There no relation of statistical significance found in this study between treatment modalities and outcome, p value 0.209 (**Table 3**). The follow up was short term up to ten weeks (mean; 3.4 ± 2.7 weeks). The follow up durations in most of patients between 1 - 3 months 19 pts (63.3%), and less frequent follow-up period is less than one month only 1 pts (3.3%).

4. Discussion

Wilm's tumour is second common solid abdominal paediatric malignancy and the commonest type of renal tumour in children. Internationally the outcome of

Table 2. Duration of the illness and outcome of treatment.

Duration (weeks)	Outcome			Total
	Uneventful	Complication	Death	
1 - 5	18 (81.8%)	1 (04.5%)	3 (13.6%)	22 (100%)
6 - 10	02 (100%)	0 (0.0%)	0 (0.0%)	02 (100%)
11+	03 (50.0%)	01 (16.7%)	02 (33.3%)	06 (100%)
Total	23 (76.7%)	02 (06.7%)	05 (16.7%)	30 (100%)

p value 0.492.

Table 3. Modalities of treatment and outcome in patients with Wilm's tumour in the study.

Outcome	Treatment			Total
	Surgery	Chemotherapy	Chemotherapy and surgery	
Uneventful	4	1	18	23
Complication	0	1	01	02
Death	2	1	02	05
Total	6	3	21	30

p value 0.209.

Wilm's tumour has significantly improved in the last two decades after adopting multi-modal approach in management of the disease in most of centre. In Sudan, the Wilm's tumour is also one of the most common abdominal malignancies children as showed by Hassan Ibrahim and Hatim Khalil studies [8] [9].

In this study, thirty patients whom satisfied the inclusion criteria were studied. The main age of most patients in the study was between 3.5 to 5.9 years. It was similar to studies done in Sudan by Abuidris DO *et al.*, and Eiman Zaki Antoun. [10] [11] In Kenya the study done by Rogers T *et al.*, in south Africa by Abdallah, F. K and Macharia W. M [12] [13] and internationally Green DM *et al.* [14] all of them have similar main age to this study. In the study the female is commonly affected by disease with male to female ratio of 1:3 which is increasing than 0.9:1 reported earlier in Sudan [10] [11] [15] and also compared to study in Pakistan by Fadoo Z *et al.* revealed that male to female ratio of 1.5:1 the median age of presentation was 4 years, [16] the reverse of this ratio is seen in Indian studied by Green DM *et al.* that showed: male to female ratio of 3:1 [17].

Most of the patients came from centre and west of Sudan 14 (46.7%), 10 (33.3%) patients respectively ,this was compared to Sudanese study done by Salih HM between 2006 and 2010 at Khartoum university resulted in Forty two percent of patients were from western Sudan, 4 (13.3%) form east and the least from north of Sudan 2 (6.7%) patients [15]. This is similar result to two other studies done in Sudan: first by Eiman Zaki Antoun [11], second study was done by Hassan Ibrahim on 2013 conducted in Khartoum teaching hospital and Soba university hospital [8]. Regarding the clinical presentations most of the patients in the study presented by abdominal mass 28 pts (93.3%), this is also similar to last study in Sudan done by Abuidris DO *et al.* reported that abdominal mass is common presentation of the disease in Sudan [10], also that matched with study done in south Africa by Rogers T *et al.* [12] and international by reported study by Green DM [18]. Also most of symptoms and signs in the study were similar in both, Sudan and international comparisons [18]. The abdominal mass associated with abdominal distension in 16 (53.3%) patients, while the abdominal pain was the less frequent abdominal symptom seen in 7 (23.3%) of the patients, anoxia presented in only 7 (23.3%) patients and the least frequent symptoms over all is blood in urine seen only in 2 (6.7%) patients. In this study the most frequent

duration of the symptoms was ranged from 1 - 5 weeks 22 (73.3%) patients. And less frequent between 6 - 10 weeks only 2 (6.7%) patients. From 11 weeks and more, 6 (20%) patients presented in this period of time. Regarding duration of symptoms, I didn't find any previous studies in Sudan approved the accurate duration of the symptoms before presented to hospital.

In the study most useful tool in diagnosis of Wilm's tumour is radiological Imaging: ultrasound scan was firstly described in most of patients 22 (73.3%), then computed tomography scan was used in almost 28 (93.3%) patients, to confirm the diagnosis and to assist evaluating the extension and invasion of Wilm's tumour. In Routine investigations the most useful was the following: low haemoglobin level is noticed in 12 (40%) patients while normal in 18 (60%) patients, haematuria seen in only 3 pts (10%) of urine analysis, blood urea and serum creatinine were noticed to be raised in only one (3.3%) and Liver function tests was not routinely used so it was requested to only 14 patients with 3 (10%) patients showed abnormality. All this data regarding the diagnostic work up were similar to international data reported by study of Green DM [19].

Confirmatory diagnosis of Wilm's tumour after high suspicion with biopsy was remained controversial, so biopsy is used in most of the study 18 pts (60%), biopsy is taken either: TCNB which is used in 9 (30%) patients, excisional biopsy in 7 (23.3%) patients and incisional biopsy only used in 2 (6.7%) patients. Different types of biopsy were taken according to each centre protocol: in SUH the TCNB is preferable option for diagnosis of Wilm's tumour firstly before starting the treatment, while KTH and GNCP used imaging to diagnosis before nephrectomy (excisional biopsy) was done, and all centres didn't use incisional biopsy except in inoperable cases for pathological diagnosis to start the palliative treatment. In comparison to international protocol there were two different accepted protocols regarding biopsy in patient with Wilm's tumour as follow: In North America, patients with suspected Wilm's tumour undergo nephrectomy first. In contrast to most European centres who make a presumptive diagnosis of Wilm's tumour based on imaging findings alone. Clinicians in Europe prefer to administer chemotherapy before nephrectomy without survival compromise as seen by study of Green DM *et al.*, at 1994 and 2004 [17]. Transcutaneous biopsy is not usually recommended and may in fact complicate the treatment by causing preoperative tumour spill, requiring whole abdominal radiotherapy as reported by Green DM *et al.*, 1994 [14] [17].

There were different treatment modalities in the study: surgery followed by chemotherapy was used in most of patients 21 (70%), while surgery alone used in 6 (20%) patients and the least used protocol is chemotherapy alone 3 (10%) patients this only used in an inoperable case. So KTH and GNPC the management protocols were all for operable patients' undergoing surgery (nephrectomy) followed by postoperative chemotherapy, while in SUH they used preoperative chemotherapy followed by nephrectomy. All Sudanese centres used the biopsy then chemotherapy in inoperable cases. This match the study in Nigeria study done by Uba AF and Chirdan LB revealed that the protocol of Nephrect-

omy and chemotherapy were the best modality of treatments [20]. In compared to International studied by Ruteshouser *et al.* the protocol of Children's Oncology Group (COG) was usual approach is nephrectomy followed by chemotherapy, with or without postoperative radiotherapy [13]. Also six patients in the study treated with nephrectomy alone, this met evidence suggests that certain children with stage I disease with favourable histology do well with nephrectomy alone as reported by Ruteshouser *et al.*, 2008 [21].

In this study, the outcome of Wilm's tumour is excellent. Uneventful discharged with good outcome was seen in 18 pts (60%), morbidity showed in only 2 pts (6.7%) and death or unknown outcome was seen in similar number of patients in 5 pts (16.7%). Internationally approximately 80% - 90% of children with a diagnosis of Wilm's tumour survive with current multimodality therapy as reported in study of Pelletier J *et al.* [12] Morbidity was seen in two patients. Deaths were occurred in five patients in the study (16.7%). Most of patients in the study continued to be followed up to first three months 19 (63.3%) patients, the least frequent follow-up period was less than one month only 1 (3.3%) patients and between 4 - 6 months and more than 7 months had been seen in 6 (20%) patients, 4 (13.3%) patients respectively.

5. Conclusions

Wilm's Tumor in Sudan has similar clinical presentations compared to international reported data. The most approached tools for diagnosis are ultrasound scan and computed tomography and also no needed for biopsied except in advanced stages of disease. Wilm's tumor in Sudan has an excellent outcome when children are managed by multimodal approach: namely nephrectomy followed by adjuvant chemotherapy.

Recommendations

Multimodal approach is the costive but only method to achieve the excellent outcome in treating this cancer, so I raise this issues to Sudan government to build special pediatric oncology centers to enhance cancer outcome.

Conflicts of Interest

None.

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The Self-Administered International Prostate Symptoms Score (IPSS) Questionnaire of Kosovo Men with Benign Prostatic Hyperplasia

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Abstract

Background: Benign prostatic hyperplasia (BPH) has been a major health problem for aging males because of its related symptoms and complications. Although it is not a life-threatening condition, BPH has an adverse effect on a patient's quality of life, as manifested in community and clinical trials. **Aim:** The aim of the study was the perception of patients in their symptomatology by comparing the place of residence and quality of life in living with HBP using the IPSS questionnaire. **Materials and Methods:** This was a prospectively designed study conducted at University Clinical Centre of Kosovo—Urology Clinic. The study was conducted from October 2020 to January 2021. The study in criteria was as follows: all patients who presented to the urology outpatient clinic with BPH, Lower Urinary Tract Symptoms (LUTS) and aged > 40 years. The exclusion criteria included the following cases: patients with uncontrolled diabetes (prostate-specific antigen > 4 ng/dL); patients with a history of transurethral resection of the prostate. **Results:** This study was carried out on 100 consecutive patients with HBP and LUTS attending. The largest proportion of patients 51% was in the 46 - 55 age group. Most patients were between 45 - 65 years of 51%. The largest number of them (52%) was with severe symptoms and 41% of them were with moderate symptoms. Comparing the three levels of IPSS and the quality of life of patients with HBP and LUTS, when asked how they would feel if they still had problems with urination, 22% said they felt upset, analyzing the categorization of patients according to IPSS: mild symptoms were Mean/SD (1.71. ± 1.113), moderate symptoms (2.9 ± 1.49) and severe symptoms (4.31 ± 1.27) p < 0.156. Statistical reliability of 64% p < 0.000 was in patients where they were interested in learning about any invasive option that would allow them to discontinue medication for LUTS. **Conclusion:** The IPSS is a valid instrument to assess the impact of

BPH symptoms on health and quality of life due to urinary symptoms.

Keywords

Benign Hyperplasia, International Prostate Symptom Score, Quality of Life, Lower Urinary Tract Symptoms

1. Introduction

Benign prostatic hyperplasia (BPH) is a common condition as men get older. An enlarged prostate gland can cause uncomfortable urinary symptoms, such as blocking the flow of urine out of the bladder. Lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) are common conditions in middle-age or older men [1]. The International Prostate Symptom Score (IPSS) is a useful and validated questionnaire to evaluate LUTS secondary to BPH [2]. However, BPH is considered for the vast majority of LUTS. BPH causes symptoms in approximately 90% of men over the age of 55 years old and one-third of men will develop urinary tract symptoms once in their life [3] [4] [5] [6].

The primary goal for treating men with BPH-LUTS is usually to relieve symptoms and to prevent them [7].

The most important issue is that the IPSS questionnaire should be self-administered as this will eliminate the possible bias that may be associated with physician-assisted or health worker-assisted administration. This instrument measures the severity of voiding and storage symptoms (see **Appendix**) and consists of 7 items of the International Prostate Symptom Score, referred to in this article as the IPSS (see **Appendix**) [8]. Therefore, guidelines recommend that the IPSS questionnaire be used as a mandatory test in the evaluation and follow-up of LUTS and BPH [9].

This study was in terms of the initial evaluation of LUTS and BPH, and the assessment of changes in symptom severity before and after medication and the quality of life of patients with benign prostatic hyperplasia.

Much of the research to date has focused to evaluate the relationship between lower urinary tract symptoms (LUTS), different diagnostic indicators of benign prostatic hyperplasia (BPH) [10], and relationship between prostate inflammation and lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) has raised the urological interest in the recent years, due to new evidence that supports this potential link [11], and some of the research has focused on surgical or medical management of symptoms, but there is growing interest in identifying preventive measures for reducing the burden of LUTS by identifying risk factors associated with these symptoms, especially those that are potentially modifiable [12]. Other risk factors include comorbidities, such as diabetes, cardiovascular disease, hypertension and the side effects of the pharmacological treatments for these comorbidities [13]. Other postulated but not yet

clearly established factors associated with LUTS include higher body mass index (BMI), lower socio-economic status, being married, family history, dietary and lifestyle factors (such as alcohol, caffeine, smoking, physical inactivity), history of sexually transmitted disease, other prostate conditions and ethnicity [11] [12] [13] [14] [15].

2. Materials and Methods

2.1. Patients and Study Design

This was a prospective, observational, study to evaluate change in QoL in patients with moderate-to-severe LUTS/BPH managed in a urological setting. The study was performed in the University Clinical Centre of Kosovo—Urology Clinic—Kosovo from October 2020 to January 2021. A total number of 100 patients who presented themselves to the urology outpatient department with LUTS due to BPH were enrolled in the study.

The study inclusion criteria were as follows: all patients who presented themselves to the urology outpatient clinic with BPH, LUTSs were aged > 40 years.

The exclusion criteria included the following cases: patients with uncontrolled diabetes (prostate-specific antigen > 4 ng/dL); patients with a history of transurethral resection of the prostate and patients who underwent surgery for urethral vesicle calculus in the past.

2.2. Sample Size

The selection of patients included in the study was randomized by analyzing inclusive and exclusion criteria.

2.3. LUTS Assessment

The collected medical histories from the enrolled patients. On their initial visit, respondents were issued IPSS (English version). The sum of IPSS questions 2, 4 and 7 related to irritative symptoms; and the sum of IPSS questions 1, 3, 5 and 6 related to obstructive symptoms.

3. Follow-Up and Outcomes

Patients with symptoms score of 20 - 35 had severe symptoms of IPSS where 52% of them were treated with Alpha Receptor Blockers, 5 alpha-reductase inhibitors and prostatectomy (TUR-P, PTV), while patients with moderate symptoms (41%) were treated with 5 alpha-reductase inhibitors and herbal extracts, and patients with mild symptoms (7%) were treated with careful observation and waiting and herbal extracts.

The questionnaire consists of seven questions on incomplete bladder emptying, frequency of micturition, intermittency, urgency, weak stream, straining and nocturia. There is an 8th question on the quality-of-life assessment in relation to the urinary symptoms.

Statistical Analysis

Values are expressed as Mean \pm SD for continuous variables and percentage for dichotomous data. Continuous data was compared with two-tailed Student *t*-test and discrete data with Chi-square test. Quantitative data was analyzed through the SPSS statistical program.

4. Results

This study was carried out on 100 consecutive patients suffering with HBP and LUTS. The average age of the participants was 69 ± 0.726 . From 100 patients surveyed 7% of them had mild symptoms, 41% had moderate symptoms and the largest number of them 52% had severe symptoms. Most of the participants (76%) were married, (90%) were Albanian. Regarding education level most of them (36%) were only educated at primary school level or below. Higher proportions of them (53%) were pensioners. 51% of them were living in a village. The majority of the participants were Muslim (92%) and (55%) of them were smokers. When asked if they use the Anti-hypertensive drugs, the majority of the patients declared yes (68%), whereas (32%) declared no. When questioned about a family history of prostate disease, 67% of them declared that they did not have a history of this in their family (**Table 1**).

Regarding the symptomatology between patients living in the city and in a village: out of 100 patients, most of them (29%) stated that they had the feeling of not emptying the bladder less than one in five times. Comparing the place of settlement, we did not find a statistically significant relationship between the settlement in the village and in the city: Village Mean-SD (2.63 ± 1.37) and Mean Rank 55.52, while Mean-SD city (2.14 ± 1.36) and Mean Rank 45.2 $p < 0.679$. In terms of frequency when comparing patients living rurally and in urban areas, we did not gain a statistically significant relationship: Village (2.61 ± 1.41), Mean Rank: 54.85, City (2.14 ± 1.30), Mean Rank 45.97 $p < 0.203$. Regarding the interval of urination, 30% of the patients had to stop and start the act of urination again. Comparing the place of residence, I did not find a statistical reliability $p < 0.338$. 24% of patients had emergency urination $p < 0.36$. Most patients, 32% of them, had low blood pressure during urination $p < 0.25$. In answer to the question: how often they have had to push or strain to begin urination, most of them (36%) had to do this almost always. We compared this with village residence: (3.25 ± 1.27), Mean Rank 54.79 and patients living in the city (2.9 ± 1.27) Mean Rank 46.03 $p < 0.256$. 28% of them urinate 2 times per night $p < 0.256$ (**Table 2**).

According to the terms of IPSS categorization most patients (52%) were experiencing severe symptoms, 41% had moderate symptoms and only 7% had mild symptoms.

Comparing the three levels of IPSS and the quality of life of patients with HBP and LUTS, when asked how they would feel if they still had problems with urination, 22% of them said that they would feel upset. Analyzing the categorization of patients according to IPSS: mild symptoms were: Mean/SD (1.71 ± 1.113),

Table 1. Main socio-demographic and health conditions results (n = 100).

Characteristics	N	%
Age		
46 - 55 years old	22	22
56 - 65 years old	47	47
>66 years old	31	31
Minimum		46
Maximum		85
Median		65
Mean (SD)		69 (± 0.726)
Marital status		
Married	76	76
Divorced	8	8
Single	16	16
Ethnicity		
Albania	90	90
Turkish	6	6
Bosnian	1	1
Egyptian	3	3
Education level		
Below primary school	36	36
Junior high school	25	25
High school or some college	36	36
University or above	3	3
Professional status		
Employed	36	36
Unemployed	11	11
Pensioner	53	53
Living place		
City	49	49
Village	51	51
Smoking		
No	45	45
Yes	55	55
If you smoke		
>10 cigarettes a day	32	32
>20 cigarettes a day	23	23
Anti-hypertensive drugs use		
Yes	68	68
No	32	32

Continued

Anti-diabetic drugs use		
Yes	22	22
No	78	78
Family history of prostate disease		
Yes	33	33
No	67	67
According to you, In general your health is?		
Very good	7	7
Good	53	53
Bad	38	38
Very bad	2	2

Table 2. Symptomatology between patient's perception to living in the center and village.

IPSS	Total Patient's (N=100)		Village (n = 51)		City (n = 49)		P
	Over the past month	N - (%)	Mean ± DS	Mean Rank	Mean ± DS	Mean Rank	
Incomplete emptying —How often have you had the sensation of not emptying your bladder completely after you finished urinating?	Not at all	4 (4)					
	Less than one time in five	29 (29)					
	Less than half the time	23 (23)	2.63 ± 1.371	55.52	2.14 ± 1.369	45.28	0.679
	About half the time	22 (22)					
	More than half the time	12 (12)					
	Almost always	10 (10)					
Frequency —How often have you had to urinate again less than two hours after you finished urinating?	Not at all	6 (6)					
	Less than one time in five	27 (27)					
	Less than half the time	23 (23)	2.61 ± 1.415	54.85	2.14 ± 1.307	45.97	0.203
	About half the time	15 (15)					
	More than half the time	25					
	Almost always	4					
Intermittency —How often have you found you stopped and started again several times when you urinated?	Not at all	3					
	Less than one time in five	13					
	Less than half the time	21	3.14 ± 1.4	55.9	2.67 ± 1.214	44.79	0.338
	About half the time	30					
	More than half the time	19					
	Almost always	14					
Urgency – How often have you found it difficult to postpone urination?	Not at all	10					
	Less than one time in five	22					
	Less than half the time	14	2.78 ± 1.419	55.69	2.22 ± 1.558	45.1	0.364
	About half the time	24					
	More than half the time	21					
	Almost always	9					

Continued

	Not at all	1					
	Less than one time in five	13					
Weak stream —How often have you had a weak urinary stream?	Less than half the time	13	3.65 ± 1.547	55.32	3.35 ± 1.284	45.48	0.038
	About half the time	11					
	More than half the time	32					
	Almost always	30					
	Not at all	3					
	Less than one time in five	10					
Straining —How often have you had to push or strain to begin urination?	Less than half the time	17	3.61 ± 1.626	54.16	3.37 ± 1.395	46.69	0.49
	About half the time	11					
	More than half the time	23					
	Almost always	36					
	None						
Sleeping —How many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	One Time	11					
	Two Times	28	3.25 ± 1.278	54.79	2.9 ± 1.279	46.03	0.256
	Three Times	20					
	Four Times	24					
	Five or More Times	17					

Moderate symptoms (2.9 ± 1.49) and severe symptoms (4.31 ± 1.27) $p < 0.156$. Statistical reliability of 64% $p < 0.000$ was in patients where they were interested in learning about any invasive option that would allow them to discontinue medication for LUTS (**Tables 3-5**).

5. Discussion

The purpose of this study is to evaluate psychometric properties including validity and quality of life patients with BPH using the IPSS instrument in male patients with BPH under tertiary care.

This study has evaluated changes in symptoms and QoL in a large cohort of patients with LUTS/BPH managed in conditions of real-life practice. We observed significant improvements in interested in learning about a minimally invasive option that could allow you to discontinue your BPH medications.

A relevant contribution of this study is that it assesses the effect on QoL of several medical treatments for LUTS/BPH used in real life practice by means of an internationally recognized, validated questionnaire that is easy to use in regular clinical practice, whereas earlier studies tended to focus almost exclusively on symptoms [16] [17] [18] or on outcomes associated with a single drug [19] [20]. In the present study, treatment regimens were chosen by participating urologists based on their current practice, and the distribution of patients across different pharmacological options is in line with data published in a previous report [18] [21].

Table 3. Quality of life and IPSS assessment.

Symptomatology and categorization		N	Mean Rank
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	1 - 7 mild symptoms	7	18.07
	8 - 19 moderate symptoms	41	38.98
	20 - 35 severe symptoms	52	63.95
	Total	100	
Have you tried medications to help your symptoms?	1 - 7 mild symptoms	7	45.5
	8 - 19 moderate symptoms	41	52.82
	20 - 35 severe symptoms	52	49.35
	Total	100	
Did these medications help your symptoms? (circle)	1 - 7 mild symptoms	7	82.93
	8 - 19 moderate symptoms	41	64.88
	20 - 35 severe symptoms	52	34.8
	Total	100	
Would you be interested in learning about a minimally invasive option that could allow you to discontinue your BPH medications?	1 - 7 mild symptoms	7	75.36
	8 - 19 moderate symptoms	41	56.89
	20 - 35 severe symptoms	52	42.12
	Total	100	

Table 4. Quality of life and IPSS assessment test statistics^{a,b}.

	If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	Have you tried medications to help your symptoms?	Did these medications help your symptoms? (circle)	Would you be interested in learning about a minimally invasive option that could allow you to discontinue your BPH medications?
Chi-Square	27.318	2.043	34.504	16.595
df	2	2	2	2
Asymp. Sig.	0	0.36	0	0.000

a. Kruskal Wallis Test; b. Grouping variable.

Table 5. Quality of life and IPSS assessment.

Quality of Life (QoL)	Variable	N - 100	1 - 7 mild symptoms		8 - 19 moderate symptoms		20 - 35 severe symptoms		P
			N - 7		N - 41		N - 52		
			Mean	SD	Mean	SD	Mean	SD	
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	Delighted	0							
	Pleased	11							
	Mostly Satisfied	22							
	Mixed	13	1.71	1.113	2.9	1.497	4.31	1.276	0.156
	Mostly Dissatisfied	22							
	Unhappy	19							
	Terrible	13							

Continued

Have you tried medications to help your symptoms?	Yes	90	0.00	0.000	0.15	0.358	0.08	0.269	0.013
	No	10							
Did these medications help your symptoms? (circle)	1	8							
	2	13							
	3	15							
	4	7	8.43	3.309	6.51	2.215	3.69	2.044	0.674
	5	12							
	6	11							
	7	6							
	8	13							
Would you be interested in learning about a minimally invasive option that could allow you to discontinue your BPH medications?	Yes	64	0.86	0.378	0.49	0.506	0.19	0.398	0.000
	No	36							

In item-total correlation testing, the symptom-related item of nocturia and incomplete emptying feeling had a poor correlation. The results suggest that this item is being measured in a related yet slightly different domain than the other items of the IPSS. This result isn't similar to that of a previous validation study carried in Brazil [19].

Some studies have already demonstrated an association between nocturia and poorer HRQoL in men with BPH. Van Dijk *et al.* [19] reported that among the symptoms assessed by the IPSS questionnaire, nocturia, urgency and weak stream associated with poorer QoL. Storage symptoms such as urgency, increased frequency, and nocturia reportedly have a greater impact on QoL than voiding symptoms [20]. In our study, nocturia (20% were three times, 24% four times and 17% five or more times), frequency (23% were Less than half the time, 15% about half the time and 25% more than half the time) and incomplete emptying (23% were less than half the time, 22% about half the time and more than half the time were 12%), had a negative impact on the QoL in men with BPH.

In this study the patient's classification according to IPSS showed that most of them 52% experienced severe symptoms, 41% had moderate symptoms and only 7% had mild symptoms. Comparing the three levels of IPSS and the quality of life of patients with HBP and LUTS, when asked how you would feel if you still had problems with urination, 22% said they would feel upset, analyzing the categorization of patients according to IPSS: Mild symptoms were: Mean/SD (1.71 ± 1.113), moderate symptoms (2.9 ± 1.49) and severe symptoms (4.31 ± 1.27) $p < 0.156$. The statistical reliability of 64% $p < 0.000$ was in patients where they were interested in learning about any invasive option that would allow them to discontinue medication for LUTS.

A study was done in Nigeria [22] to determine the value of IPSS in the management of patients with BPH. Using pre-treatment IPSS, patients were divided

into 3 groups: mild, moderate, and severe symptoms groups. Patients with mild symptoms were treated with careful observation and waiting as a mode of management. The moderate symptoms group received doxazosin (a-blocker) & antimuscarinics, while the severe symptoms group was treated by prostatectomy. The positive predictive value (PPV) of post treatment symptoms improvement was found out to be 87% for the severe group and 52% for the moderate group as measured by IPSS/QOL [23]. The study concluded that IPSS is a valuable tool in management of patients with BPH.

Limitations

Subjects in the present study were only recruited by a convenience sampling in Urology Clinic. The psychometric performance of these measures should be further tested with Albania speakers of different nationalities as all subjects in this study were knew Albanian speakers.

6. Conclusion

The results demonstrate that IPSS is reliable, shows responsiveness, and has constructive validity. The IPSS is a valid instrument to assess the impact of BPH symptoms on health and quality of life due to urinary symptoms.

This assessment measures the quality of life of living with benign prostatic hyperplasia according to the IPSS scale classification.

Conflicts of Interest

None.

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Appendix

International Prostate Symptom Score (IPSS)

Patient Name: _____

Today's Date: _____

Determine Your BPH Symptoms

Circle your answers and add up your scores at the bottom.

Over the past month	Not at all	Less than one time in five	Less than half the time	About half the time	More than half the time	Almost always
Incomplete emptying – How often have you had the sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
Frequency – How often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
Intermittency – How often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5
Urgency – How often have you found it difficult to postpone urination?	0	1	2	3	4	5
Weak stream – How often have you had a weak urinary stream?	0	1	2	3	4	5
Straining – How often have you had to push or strain to begin urination?	0	1	2	3	4	5
Sleeping – How many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	None 0	One Time 1	Two Times 2	Three Times 3	Four Times 4	Five or More Times 5
Add Symptom Scores:		+	+	+	+	+

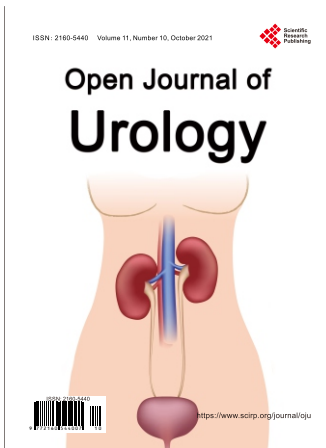
Total International Prostate Symptom Score = _____

1 – 7 mild symptoms | 8 – 19 moderate symptoms | 20 – 35 severe symptoms

Quality of Life (QoL)

Regardless of the score, if your symptoms are bothersome you should notify your doctor.

	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible		
If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?	0	1	2	3	4	5	6		
Have you tried medications to help your symptoms?						Yes	No		
Did these medications help your symptoms? (circle)									
1	2	3	4	5	6	7	8	9	10
No Relief						Complete Relief			
Would you be interested in learning about a minimally invasive option that could allow you to discontinue your BPH medications?						Yes	No		



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