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Outcomes of patients undergoing radical hysterectomy for early-stage cervical cancer at Bugando Medical Centre, Mwanza – Tanzania

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Keywords: Cervical cancer; Radical hysterectomy; Treatment outcomes; Tanzania.

Abbreviations: BMC: Bugando Medical Centre; CFR: Case fatality rate; CUHAS: Catholic University of Health & Allied Sciences; DFS: Disease Free Survival; HIV: Human Immunodeficiency Virus; IOR: Interquartile Range; OS: Overall Survival.

Abstract

Background: Cervical cancer is the fourth most common cancer among women worldwide. In Tanzania, it is the leading malignancy in women with 58% of deaths reported annually. Radical hysterectomy is the recommended treatment for early-stage cervical cancer, but this option only became available at Bugando Medical Centre (BMC) in 2014. The purpose of this study is to provide insight into the efficacy of gynecologic oncology surgery at BMC.

Methods: This is a 5-year retrospective chart review of all patients who underwent radical hysterectomy at BMC between January 2014 and May 2018. Coding data was scripted a priori to provide consistent and accurate data. Microsoft Excel 2007 and STATA version 13 were used for quantitative statistical analysis. Data were summarized in proportions and frequency tables for categorical variables. For continuous variables, data were reported as mean ± Standard Deviation (SD) or IQR. A chi-square test was performed to test for significant associations between the predictor and outcome variables. A significant association was defined as a p-value of less than 0.05.

Results: Sixty-two charts were available for review. The medianage was 49.5 [IQR: 42–57] years. Tumorsin lymph nodes, parametria, and vagina were detected in 12.9%, 9.7%, and 24.2% respectively. Twenty patients (30.6%) had intraoperative complications while seventeen patients (27.4%) presented with early and late postoperative complications. Intraoperative complications were: Hemorrhage (16.1%), ureteral injury (8.1%), and mortality (1.6%) while fistula and bladder dysfunction occurred in 8.1% of patients as early and late complications. The overall cancer survival rate was influenced by tumor size and was predictive of the likelihood of tumor recurrence (P = 0.013).

Conclusions: Radical hysterectomy for early cervical cancer treatment in a low-resource setting provides outcomes equivalent to well-resourced settings.

Background

Cervical cancer is the fourth most common cancer among women worldwide with an estimated 528,000 new cases and 266,000 deaths annually [1]. Over 85% of cases occur in Sub-Saharan Africa with an overall mortality rate of 22.5 per 100,000 women per year [1,2]. Tanzania has the highest incidence of cervical cancer among East African countries with an age-standardized rate of 54.0 per 100,000 women per year [1]. It is the leading cause of cancer deaths in the country with an estimated 7,304 new cases annually and 4,216 deaths per year [3]. In 2011 over 300 sites of cervical cancer screening were launched in Tanzania including Bugando Medical Centre (BMC) which contributes to a slight increase in early-stage disease (stage IA-IIA) detection [4]. At BMC, approximately 400 patients with cervical cancer are seen per annum and 52.7% present at an early disease stage IA-IIA [5,6]. There are two methods of treating cervical cancer at early stages (IA-IIA); treatment with either chemoradiation or radical hysterectomy with both modalities having similar outcomes in terms of overall survival [7,8]. In Tanzania, there are significant barriers to cervical cancer care and one of these is the lack of access to modern cancer treatment modalities [4]. When Bugando Medical Center first started treating early stage cervical cancer with radical hysterectomy, the only radiation center in the country existed in Dar es Salaam which is 1,200 km from Mwanza City. Fortunately, in 2017 Bugando Medical Centre became the second radiation Center in Tanzania and is now able to offer comprehensive care for early and late stages of cervical cancer.

The advantages of radical hysterectomy over radiation is the potential to preserve ovarian function, vaginal pliability, and improved pathological staging to identify patients who would benefit from adjuvant therapy [9]. In well-resourced settings, the procedure is associated with a 5-year survival rate of 87% - 92%, disease recurrence of 25%, and operative mortality of <1% [10,11]. However, in all settings, this procedure is associated with intra-operative and post-operative complications such as hemorrhage, injury to the urinary bladder, ureter, great vessels, bowel perforation, urinary fistula, wound sepsis, and short and long term bladder dysfunction [12,13].

At Bugando Medical Centre (BMC), this option only became available in 2014. Since the inception of this practice at BMC, a number of undocumented complications have been observed. However, little is known about the rate of complications and the outcomes of these patients. The goal of this study is to ascertain baseline data at the hospital to help the department assess the quality of care provided to patients undergoing radical hysterectomies and to improve surgical outcomes.

Methods

This was a 5-year retrospective case review study of patients confirmed to have early-stage cervical cancer who underwent radical hysterectomy from January 2014 to May 2018 at BMC. BMC is a 947-bed tertiary, consulting, and teaching hospital located in the Lake Zone in Northwestern Tanzania. It serves 8 regions with a population of about 13 million people [14]. The hospital has one gynecological oncologist trained to perform radical hysterectomies. The oncology department has two additional medical oncologists, and one radiation oncologist. The oncology department offers screening services, treatment with external beam radiation, intra-cavitary radiation and chemotherapy. The selection criteria for surgery follows FIGO (The International Federation of Gynecology and Obstetrics - 2009) clinical staging I and IIA, with no major comorbidities, and ability to afford surgical fees. About 1–2 cases of radical hysterectomy are done monthly for patients with early-stage cervical cancer. The patients who are included in this study had early stage cervical cancer and underwent a radical hysterectomy for treatment; patients who underwent radical hysterectomy for other gynecologic pathology were not included.

Data was extracted using a structured data collection tool in form of checklist developed a priori. The second author used the checklist to code each patient's chart. Data included sociodemographic and clinical characteristics including primary diagnosis, stage at presentation, age, number of children, residence, marital status, occupation, education level, parity, pathology of tumor, and documented intraoperative and post-operative complications. Early complications were those that occurred intraoperative and within 30 days of surgery and late complications were those that occurred after 30 days of surgery.

The data were put into Microsoft Excel 2007, and then STATA version 13 was used to analyze them. Categorical variables were summed up using proportions and percentages, while continuous variables were analyzed using means, medians, and standard deviations. Fisher's exact test was used to predict the relationship between tumor characteristics and patient outcomes. A p-value of less than 0.05 was considered statistically significant. A table of frequency and percentage was used to figure out how many patients survived each year after surgery. The Joint Catholic University of Health and Allied Sciences and Bugando Hospital (CUHAS/BMC) ethical, research and publication committee (CREC/338/2019) gave this study the green light in terms of ethics.

Results

During the study period, from January 2014 to May 2018, 69 patients underwent radical hysterectomy for management of early cervical cancer at BMC. Seven case files were missing, hence only 62 patient charts were included in the final analysis. The median age of women was 49.5 [IQR: 42–57] years; the youngest patient in the study was 26 years of age. Among these, 43 (69.3%) were from rural areas, 39 (62.9%) were small scale farmers.Most of them 45 (72.6%) were para five and above. (Table 1).

Clinical presentation

In this study, the majority of patients 59 (95.2%) presented with abnormal vaginal bleeding. Nineteen (30.7%) of patients needed blood transfusion during and after surgery. The average duration of surgery and hospital stay was 3 hours and 4 days respectively. Five patients (8.1%) were HIV positive (Table 2).

Tumor characteristics

Of the total 62 patients, 49 (79.0%) had squamous cell carcinoma, 12 (19.4%) had adenocarcinoma, and 1 (1.6%) had clear cell carcinoma. Forty four (71%) patients were FIGO stage IB. Most patients 39 (62.9%) had moderately differentiated histol-

Table 1: Patients socio-demographic characteristics (N=62).

Patient characteristics	Number (n)	Percentage (%)
Age group		
26- 44 years	20	32.3
45- 75 years	42	67.7
Marital status		
Married	55	88.7
Single/ widowed	7	11.3
Residence		
Urban	19	30.7
Rural	43	69.3
Occupation		
Small Scale farmer	39	62.9
Housewife	8	12.9
Merchants	2	3.2
Civil Servant	13	21.0
Education level		
No formal education	15	24.2
Primary	30	48.4
Secondary	9	14.5
College	8	12.9
Parity		
Nulliparous/ Primipara	1	1.6
Multipara	16	25.8
Para 5 and above	45	72.6

Table 2: Clinical characteristics.

Patient variables	Number (n)	Percentage (%)
HIV status		
Negative	53	85.5
Positive	5	8.1
Unknown	4	6.4
Other comorbidities		
Hypertension/ Diabetes	9	14.5
Peptic ulcer disease	2	3.2
None	51	82.3
Abnormal vaginal bleeding		
Yes	59	95.2
No	3	4.8
Abnormal vaginal discharge		
Yes	28	45.2
No	34	54.8
Lower abdominal pain		
Yes	30	48.4
No	32	51.6
Hospital stays		
≤ 4 days	41	66.1
> 4 days	21	33.9
Blood transfusion		
Yes	19	30.7
No	43	69.3
Estimated blood loss		
< 1000 mls	47	75.8
≥ 1000 mls	15	24.2
Duration of surgery		
< 3 hours	19	30.7
≥ 3 hours	43	69.3

ogy. 66.1% had a tumor size of less than 4 cm. Eight of the 62 patients had lymph node involvement (12.9%), six (9.7%) had tumor involvement at the vaginal margin, and fifteen patients (24.2%) had parametrial involvement (Table 3). Details of intra-operative complications are provided in Table 4.

Post-operative complications were defined as early if they occurred within 30 days of surgery and were deemed late complications if they occurred after 30 days of surgery. Complications were observed in 17 patients (27.4%). Of these, 11 (17.7%) occurred early and 6 (9.7%) occurred late. These are detailed in Table 4. Five patients (8.1%) developed anureterovaginal fistula and four (6.5%) had peritonitis as an early post-operative complication. Bladder dysfunction occurred in five patients (8.1%) and was the leading late post-operative complication (Table 4). All patients with fistula and bladder dysfunction recovered well after surgery and conservative management respectively.

Table 3: Tumor characteristics of patients who underwent radical hysterectomy

Variable	Number (n)	Percentage (%)
Clinical staging before surgery		
I A	8	12.9
I B	44	71.0
II A	10	16.1
Histological type		
Squamous cell carcinoma	49	79.0
Adenocarcinoma	12	19.4
Clear cell carcinoma	1	1.6
Grade of differentiation		
Grade 1	23	37.1
Grade 2	39	62.9
Grade 3	0	0.0
Tumor size		
< 4 cm	41	66.1
≥ 4 cm	21	33.9
Parametrial involvement		
Yes	15	24.2
No	47	75.8
Vaginal margins involvement		
Yes	6	9.7
No	56	90.3
Lymph node involvement		
Yes	8	12.9
No	54	87.1

Outcomes of patients after radical hysterectomy

Out of the initial sample of 62 patients, nine were lost to follow-up during the study's duration. Therefore, only 53 patients have their survival rates recorded after a full year of follow-up after surgery. Patients who underwent surgery within two years of the coding date had a 100% chance of survival. However, the survival percentage drops to 57% for individuals who had surgery before the end of the fifth year (at the time of coding). Similarly, disease-free survival was best in the first few years after surgery, and recurrence was common beyond three years. At the time of coding, 40 patients (75.7% of the total)

Table 4: Complications of radical hysterectomy.

Variables	Number	Percentage (%)
Complications Intraoperative complications		
Yes	20	30.6
No	42	69.4
Types of complication		
Ureteric injury	5	8.1
Bladder injury	2	3.2
Blood vessel injury	2	3.2
Hemorrhage	10	16.1
Death	1	1.6
Post-operative complication		
Yes	17	27.4
No	45	72.6
Early postoperative complication		
Yes	11	17.7
No	51	82.3
Complications		
Fistula	5	8.1
Peritonitis	4	6.5
Ureteral obstruction	1	1.6
Wound infection	1	1.6
Late postoperative complication		
Yes	6	9.7
No	56	90.3
Complications		
Bladder dysfunction	5	8.1
Bladderandrectum dysfunction	1	1.6

were deemed to be disease-free, while 8 patients (15%) developed a recurrence of their malignancy. There were five deaths throughout the study period, and it is not apparent if all of them were related to the condition being studied (Table 5).

Grade, size, and regional dissemination of the tumor are related to patient outcomes, which are detailed in Table 6. Noted above is the finding that tumors larger than 4 cm in diameter were only significantly associated with a poor prognosis (P =0.013).

Table 6: Tumor Characteristics and Patient Survival (n = 53).

Patient variable	Patient outcome			
	Disease free	Died	Recurrence	p – value
Grade				
I	16(84.2)	2(10.5)	1(5.3)	0.377
II – III	24(70.6)	3(8.8)	7(20.6)	
Figo stage				
< IB	5(83.3)	0(0.0)	1(16.7)	1.000
≥ IB	35(74.5)	5(10.6)	7(14.9)	
Histology				
SCC	31(75.6)	3(7.3)	7(17.1)	0.640
None SCC	9(75.0)	2(16.7)	1(8.3)	
Tumour size				
< 4cm	30(88.2)	2(5.9)	2(5.9)	**0.013**
≥ 4cm	10(52.6)	3(15.8)	6(31.6)	
Lymph node				
Positive	6(85.7)	0(0.0)	1(14.3)	1.000
Negative	34(73.9)	5(10.9)	7(15.2)	
Parametrium				
Involved	9(64.3)	3(21.4)	2(14.3)	0.236
Not involved	31(79.5)	2(5.1)	6(15.4)	
Vaginal margins				
Involved	2(50.0)	0(0.0)	2(50.0)	0.143
Not involved	38(77.6)	5(10.2)	6(12.2)	

Discussion

The results of this radical surgical hysterectomy for locally advanced cervical cancer in Tanzania are the first to our knowledge. Hemorrhage, ureteric injury, and bladder injury were the most common intraoperative problems in this review, affecting one-third of patients. Almost similar complications at varying rates have been documented in Nepal, Turkey, and the United States [15-17]. However, complication rates differ depending on study design, type of radical hysterectomy (open or minimally invasive), tumor size, institutional experiences, and stage of the disease. In this chart review, the rate of complications was slightly higher than in Turkey and the United States [16,17] since our team has less experience and all our patients were operated on via open radical hysterectomy which has higher incidences of hemorrhage compared to minimally invasive procedures such as laparoscopic and robotic radical hysterectomy [18,19]. Another reason of higher rates of intraoperative

Table 5: Patient outcomes.

		Survival outcomes					
Surgery Year*	**Number of Cases per Year**	**Lost to follow up**	**Present at follow up**	**Alive (surviving at time of coding)**	**Dead**	**Disease Free Survival (%)**	**Recurrence (%)**
Year 5	13	6	7	4 (57.1)	3	3 (42.9)	1 (14.3)
Year 4	12	1	11	10 (90.9)	1	7 (63.6)	3 (27.3)
Year 3	10	1	9	8 (88.9)	1	6 (66.7)	2 (22.2)
Year 2	20	1	19	19 (100)	0	17 (89.5)	2 (10.5)
Year 1	7	0	7	7 (100)	0	7 (100)	0 (0.0)
*Total***	62	9	53	48 (90.6)	5	40 (75.7)	8 (15.1)

*year since surgery at time of coding (2014 -2018).

**total number of cases and their outcomes regardless of years of follow up at time of coding.

complications is due to larger tumor sizes of more than 4 cm in one third of all operated cases. A retrospective review of 1,415 patients found that blood transfusion was required in 27% of patients with tumor size more than 4 to 6 cm plus higher rates of parametrial and lymph nodes metastasis [20]. In 2018, FIGO recommended to evaluate tumor size radiologically prior to making a treatment decision knowing that the precise tumor size could only be determined during final pathological examination [21]. MRI and PET CT scans were not available during the study period, thus we recommend that the decision for surgery be made on an individual basis taking into account professional skills, patient characteristics, and the availability of infrastructure at the facility.

Early and late postoperative complications occurred in approximately a third of our patients. Ureteric fistulas and bladder dysfunction were the leading complications. Similar findings with different rates have been reported in China, Turkey and United States [16,19,22]. All rates are institution dependent and dependent on sample size, expertise, and surgical approach. We also noted several other postoperative complications at lower rates such aswound infection, peritonitis, bladder dysfunction, hydronephrosis, and bowel dysfunction which have been reported in other studies [16,22-24]. Most of our postoperative problems were successfully treated with either additional surgery or medication, and the patients recovered well. There was one intraoperative death from bleeding to death, but no other deaths occurred as a result of surgery or its immediate after math. As surgical expertise improves, we expect fewer complications in the future.

The survival rate for patients who underwent radical hysterectomy depends on the disease stage, tumors size, grade of disease, lymph node involvement, positive parametrial margins, and positive vaginal margins which are all previously well documented in the literature [25-27]. The overall disease rate and disease free survival rate after radical hysterectomy for early stage cervical cancer is reported to range from 80% - 95% and 75.2% - 97.4% respectively in studies done in Italy, USA, Turkey [28-30]. In a similar vein, this chart review found a 90.9 percent overall survival and a 75.5 percent disease-free survival rate regardless of years of follow-up. In the course of doing our annual evaluation over the previous three years, we have uncovered several encouraging findings. We have seen an increase in the percentage of patients who are surviving the disease as well as a decrease in the number of individuals whose cancer has returned. The overall survival percentage is 100% for individuals who have only undergone surgery within the past two years. Out of the 27 patients who have undergone surgery in the past two years, two patients have experienced a recurrence of their disease, and just one patient has been lost to follow up. These findings may be a result of the development of a radiation unit during the same time period, which spared patients from having to be referred for adjuvant therapy to another radiation center located more than 1,200 kilometers away. It's possible that one of the most important factors in this improvement is an increase in the surgical expertise of the surgeons who work alongside the lone gynecologic oncology-trained surgeon.

In East Africa, there is a dearth of information pertaining to the outcomes of treatment for early invasive cervical cancer, and data pertaining specifically to surgery is nonexistent. Radiation therapy is the only treatment for cervical cancer that has outcomes data available for all stages of the disease. For instance, at Kenyatta National Hospital (KNH), between the years 2008 and 2010, 355 patients with histologically confirmed cervical cancer received radiotherapy. Of those patients, 18.0 percent presented in early disease stage I-II; the median survival for FIGO Stage I was 21 months, while the median survival for stages II was 18 months; 41.1 percent were unable to be followed up with, and overall survival at two years was 20 percent across all stages combined [31]. In Kampala, Uganda, between 1995 – 1997 overall survival at 3 years stands at 52.4%, while 28.4% lost to follow-up and 39.8% were at early stage I-IIA [32]. The prognosis of Ugandan cancer patients was generally very poor with 5-year absolute survival after treatment was 15.9% between 1993 to 1997 [33]. Radiation therapy and surgery are understudied in Tanzania for the treatment of early invasive cervical cancer.

The results of this chart review suggest that women with early-stage IA-IIA cervical cancer who have a radical hysterectomy for a tumor less than 4 cm have good outcomes and survival rates similar to those reported in well-resourced settings [34]. The 2009 FIGO staging method was used for our radical hysterectomy at BMC during the study period. This has a number of problems, such as the fact that imaging modalities to find positive lymph nodes, parametria, and tumor size are optional, and there is no clear indication for a treatment modality for early-stage cancer with a tumor size of more than 4 cm. Patients with tumors bigger than 4 cm, positive lymph nodes, and involvement of the genitalia need adjuvant therapy, which is linked to more side effects and a lower chance of survival. In this study, all of the patients with these traits got extra radiation, which may have contributed to the bad outcome.

Currently, thorough evaluation either clinically or via imaging technology before embarking on radical hysterectomy is recommended [7]. Nevertheless, this is a significant obstacle in situations with restricted access to resources, such as those that have fewer or no treatment alternatives, less surgical or pathological knowledge, and fewer imaging tools. Chemotherapy has been offered at BMC since 2012, surgical treatment options have been available since 2014, and radiation therapy using cobalt 60 has been available at BMC since 2017. These developments have led to significant progress in the treatment of cancer. We strongly encourage the expansion of treatment options for early-stage invasive cervical cancer, and we believe that radical hysterectomy is the best option because it is easy to access, has a low cost in terms of training, implementation, and maintenance, and most importantly, has promising survival outcomes that are comparable to those in high-income countries.

Limitations

Small sample sizes make it hard to generalize the information. There were more than two chart coders involved in coding the only information that was available, which may not have been accurate. Lastly, a large number of patients were followed for less than 5 years, which changes how the survival results should be interpreted.

Conclusion

According to the findings of this research, radical hysterectomy combined with bilateral pelvic lymph node dissection is associated with a low risk of post-operative complications and a high probability of patient survival. As a result, we suggest that the treatment be reexamined in a subset of East African women who have been diagnosed with cervical cancer in an early stage.

Declarations

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Authors' contribution: EN, EMC, DM and HD participated in designing the work, data collection, data analysis and did several reviews of the manuscript. FM, AK participated in designing the work.

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