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Original Research Article

Factors Influencing Early Treatment Outcomes among Patients with Cholangiocarcinoma at Muhimbili National Hospital, Tanzania: A Retrospective Hospital Based Cross Sectional Study

Lukiza Julius Kamhabwa[1,2,3*], Timon Theophil Theonest[4], Ally Mwanga[2], Victor Ngotta[2], Mabula Mchembe[2]

[1]Department of Surgery, Muhimbili University of Health and Allied Sciences, MUHAS, P O Box 65001, Dar es Salaam, Tanzania
[2]Department of Surgery, Muhimbili National Hospital, MNH, P.O Box 65000, Dar es Salaam, Tanzania
[3]Department of Surgery, Iteja District Hospital, Misungwi, P.O BOX 08, Mwanza, Tanzania
[4]Department of Obstetrics and Gynecology, Bukoba Regional Referral Hospital, P.O BOX 265, Bukoba, Tanzania

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Abstract: ***Background***: Cholangiocarcinoma (CCA) is the disease of public health importance due to the increase in number of cases in the last 30 years. Because of its late presentation of the disease has been associated with worse outcomes. Moreover, treatment options are limited due to the complexity of the condition. There are limited studies on the subject matter in our country; therefore, this study aims to assess factors influencing treatment outcomes among patients with cholangiocarcinoma treated from January 2017 to December 2021 at MNH. ***Results***: This study that involved 108 case notes of patients with cholangiocarcinoma. Female patients were 57 and male 51. It was found that median age at diagnosis was 59. It was shown by using radiological imaging (CT scan and MRCP) that majority of patients had perihilar cholangiocarcinoma 76 (71%) followed by distal cholangiocarcinoma 20(18.7%). On metastasis 54(50%) patients had metastasis and the leading organ of metastasis being the liver 40 (74.1%). Only 46 were checked for CEA and 37 were checked for CA19-9 pre intervention and less than 5% post intervention. Study revealed that 9 (8.33%) patients were treated surgical. out of 73 patients, majority 63 (86.3%) patients had no complication after treatment, only 10 (13.7%) patients developed complications. Among 10 patients developed the following complications; peri-catheter leak after (PTBD) 4 (40%), anastomotic leak 2 (20%), SSI 1 (10%) and others (pulmonary embolism, catheter occlusion) 3 (30%) patients. Furthermore, out of 73 patients, the mortality of the patients post intervention were 7 (9.6%) patients. On factors associated with early treatment outcomes, it was revealed that; patients with more than 50 years 9 (15%), perihilar cholangiocarcinoma 8 (15.1%) and metastasis of the tumor 5 (16.1%) had complications. It was shown that there was no significant difference on factors associated with complication after intervention. ***Conclusion*:** This study concluded that there was no statistical significant association between factors associated with early treatment outcome among patients with cholangiocarcinoma. This study revealed that CCA is a malignancy that has challenge to treat and most of patients were presenting in metastatic disease 50%.

Keywords: Cholangiocarcinoma, Treatment Outcomes, Metastasis, CEA, CA19-9, PTBD.

BACKGROUND

Cholangiocarcinoma (CCA) is a malignancy of the biliary tract that can occur either in the liver (intrahepatic) or in the extrahepatic bile ducts which are of increasing due to its continually increasing incidence worldwide [1].Types of CCA based on the anatomical location: intrahepatic CCA (iCCA), perihilar CCA (pCCA), and distal CCA (dCCA). It estimated to be 3% of all gastrointestinal system cancers [2]. iCCAs arise above the second-order bile ducts, whereas the anatomical point of division between perihilar cholangiocarcinomas (pCCAs) and distal cholangiocarcinomas (dCCAs) is the cystic duct [3]. pCCA accounts for 50% to 60% of all CCA, dCCA for 20% to 30%, and iCCA accounts for 10% of all primary liver malignancies, after hepatocellular carcinoma

***Corresponding Author:** Dr. Lukiza Julius Kamhabwa
Department of Surgery, Muhimbili University of Health and Allied Sciences, MUHAS, P O Box 65001, Dar es Salaam, Tanzania

(HCC), CCA is the second most common primary hepatic cancer [4].

CCA is far more common in areas of the Eastern world than in the West, with substantial variances even within regions within the same country. These disparities in incidence are likely due, at least in part, to variances in geographical risk factors [5].

The high incidence of CCA has been documented in Asia whereby Thailand accounts for 22.9cases per 100000 persons [6], South Korea accounting for 7.5 cases per 100000 person [7], China accounting for 5.6 cases per 100000 persons, respectively while the low incidence was seen in the United States and Europe whereby the United States 3.4 cases per 100000 persons [8], France1.6cases per 100000 persons [9], and the United Kingdom accounting for 1.3 cases per 100000 persons, while in Italy 1.2 cases per 100000 persons [10]. Australia has one of the lowest documented incidences of CCA, with only 0.7 cases per 100,000 men, compared to the highest incidence of 96 cases per 100,000 men in northeast Thailand.

In sub- Saharan Africa, there are limited studies on CCA; a study conducted in Egypt showed that patients who had distal CCA constituted 52.2%, while hilar CCA 37%, and intrahepatic CCA 10.8% [11]. Variations in risk factors, notably host and environmental risk factors, account for heterogeneity in the global incidence of CCA [12]. Since CCA incidence rates vary widely around the globe, and this variation is linked to the distribution of risk factors and most likely reflects the interaction of genetic differences and geographical risk factors,. There is insufficient epidemiological data available to determine which patients are at a higher or lower risk of developing this cancer. It is well established that chronic biliary tree disease, such as primary sclerosing cholangitis (PSC), predisposes to CCA [11].

Jaundice (78 percent), anorexia (57 percent), weight loss (52 percent), stomach discomfort (44 percent), abdominal mass (44 percent), itching (25 percent), vomiting (9 percent), and fever are the most prevalent symptoms among CCA patients (7 percent). Furthermore, 98% of extrahepatic cholangiocarcinoma patients are jaundiced (63 percent of perihilar tumor patients and 35% of distal tumor patients), in contrast, just 2% of intrahepatic patients are usually jaundiced [13].

CCA is typically diagnosed using a combination of clinical, biochemical, radiological, and histological data. For the diagnosis of each CCA subtype, different imaging modalities may be used: ultrasound (US), computed tomography (CT), magnetic resonance imaging/ magnetic resonance cholangiopancreatography (MRI/MRCP), and positron emission tomography(PET) for iCCA, MRCP for pCCA and dCCA, percutaneous transhepatic cholangiography for pCCA, and endoscopic retrograde cholangiopancreatography or endoscopic ultrasound for dCCA. Because of the position of the tumors and the danger of peritoneal seeding, histological investigation is not usually recommended to confirm the diagnosis. Although it can provide significant information for clinical care of patients. Furthermore, non-specific tumor biomarkers such carbohydrate antigen 19-9 (CA19-9) are routinely detected in the blood to aid in the diagnosis of CCA, although they are inaccurate because to their limited sensitivity and specificity, especially in the early stages of the disease [14].

For tumor infiltration of arteries and veins, computed tomography (CT) has a high sensitivity [15]. It is critical to use all of the locally available imaging modalities to establish the anatomical conditions and tumor burden prior to the planned CCA resection. Imaging can also be used to identify the tumor type according to Bismuth and Corlette, as well as the tumor location regarding the confluence of the right and left hepatic ducts [16]. However, neither the Bismuth–Corlette system nor the commonly used TNM classifications are sufficient to determine the appropriate treatment or predict the prognosis in the case of pCCA [17].

Regarding treatment, surgery is the mainstay of curative treatment for patients with CCA, however, fewer than one-third of patients are resectable at diagnosis because of delayed presentation to the health facility [18]. Cillo and colleagues explained that the curative treatment for cholangiocarcinoma patients is surgical resection, nevertheless many patients with cholangiocarcinoma are not candidate for surgical resection because of metastatic or locally advanced disease at the time of presentation [19]. Among the early management outcome encountered in many studies are; sepsis [13], high fever, jaundice, chills, right upper quadrant pain, rebound tenderness, sepsis, and shock [20], delayed gastric emptying, infectious complications, and biliary complications [21].

METHODOLOGY

Study Design

This was a retrospective hospital based, cross sectional study. This study design was chosen because it allows the investigator to formulate ideas about possible associations and investigate potential relationships**.** The duration of the study was from January 2022 to May 2022.

Data Collection

Study participants were identified using ward registries. Data were collected from the file and electronic medical records using a checklist. Information on the clinical characteristics, therapeutic options received whether surgical, non-surgical (PTBD) or neither surgical nor non-surgical (PTBD) and the early

treatment outcomes were extracted for analysis. All data were collected on exit (discharge or death) for those admitted in the surgical wards and those attending interventional radiology departments as outpatients to ensure completeness of data.

Data Analysis

SPSS version 24 was used to enter and evaluate the gathered data. Frequencies and proportions were used in the descriptive analysis. For inferential statistics, the Chi-square test was performed, and a $P<0.05$ was considered statistically significant.

RESULTS

Socio-Demographic Characteristics of Study Participants

The study involved 108 patients. Majority of the patients aged more than 50 years were 84 (77.8%), with the median age of 59 years. About 57 (52.8%) Females were diagnosed to have CCA compared to males 51 (47.2%). Male to female ratio was 1:1.12. Results in table 1.

Clinical Characteristics of Study Participants

All patients presented with jaundice 108 (100%) and itching 108 (100%). Other clinical characteristic were clay colored stool 107 (100%), abdominal pain 107 (99.1%) and deep colored urine 107 (99.1%). The most common anatomical location of the cholangiocarcinoma in patient was perihilar region 76 (71%) followed by distal region 20 (18.7%) and lastly intrahepatic region 12 (10.3%). Half of the patients 54 (50%) with the disease it was found that the cholangiocarcinoma metastasized in other body sites. Furthermore the commonest site of metastasis was the liver 40 (74.1%). Results in table 1.

Table 1: Demographic and clinical characteristics of the study participants, (N=108)

Variable	Frequency (n)	Percent (%)
Age group (years)		
< 50	24	22.2
≥ 50	84	77.8
Median age in years (IQR)	59 (50, 66)	
Sex		
Male	51	47.2
Female	57	52.8
Clinical symptoms		
Jaundice	108	100.0
Itching	108	100.0
Clay colored stool	107	100.0
Abdominal pain	107	99.1
Deep colored urine	107	99.1
Other symptoms	54	50.0
Anatomical location of		
Intrahepatic	12	10.3
Perihilar	76	71.0
Distal	20	18.7
Metastasis		
Yes	54	50.0
No	54	50.0
Sites of metastasis (n = 54)		
Liver	40	74.1
Gall bladder and liver	3	5.6
Liver and lungs	3	5.6
Pleural	3	5.6
Bone	1	1.9
Gall bladder	1	1.9
Liver and head of pancreas	1	1.9
Liver and pleural	1	1.9
Supraclavicular lymph node	1	1.9

Tumor Markers of Patients with Cholangiocarcinoma

Out of 108 only 83 patients had CEA and CA 19-9 test from the laboratory. The most common tumour marker was the CEA in 46 (42.6%) patients with mean of 52.5±188.21 followed by CA 19-9 in 37 (34.3%) patients with the mean of 668.08±991.35. Results in table 2.

Table 2: Laboratory findings of the patients with cholangiocarcinoma

Variable	Total N=108	Mean
CEA	46	52.5±188.21
CA19-9	37	668.08±991.35

Treatment Outcomes of Cholangiocarcinoma among Patients at MNH

In results in table 5, out of 73 patients, majority 63 (86.3%) patients had no complication after treatment, only 10 (13.7%) patients developed complications. Among 10 patients developed the following complications; peri-catheter leak after (PTBD) 4 (40%), anastomotic leak 2 (20%), SSI 1 (10%) and others (pulmonary embolism, catheter occlusion) 3 (30%) patients. Out of 59 patients, 38 (64.4%) stayed at hospital for the period less than 14 days while 35.6% had stayed for more than 14 days. Furthermore, out of 73 patients, the mortality of the patients post intervention were 7 (9.6%) patients. Results in table 3.

Table 3: Treatment outcomes among patients with cholangiocarcinoma

Variable	Frequency (n)	Percent (%)
Outcomes n= 73		
No complication	63	86.3
Complication	10	13.7
Type of Complication (n = 10)		
Surgical sites infection	1	10.0
Anastomotic leak	2	20.0
Peri-catheter leak	4	40.0
Other	3	30.0
Hospital stay (n = 59)		
(< 14days)	38	64.4
(≥ 14 days)	21	35.6
Mortality post intervention n= 73		
Yes	7	9.6
No	66	90.4

Factors Associated with Early Treatment Outcome

On factors associated with early treatment outcomes, it was revealed that; patients with more than 50 years 9 (15%), perihilar cholangiocarcinoma 8 (15.1%) and metastasis of the tumor 5 (16.1%) had complications. It was shown that there was no significant difference on factors associated with complication after intervention. Results in table 4

Table 4: Factors associated with early treatment outcome (n=73)

Variable	Complication n(%)		p- value
	Yes	No	
Age group (years			
< 50	1(7.7)	12(92.3)	0.679
≥ 50	9(15.0)	51 (85.0)	
Anatomical location			
Intrahepatic	0(0.0)	6 (100.0)	0.865
Perihilar	8(15.1)	45 (84.9)	
Distal	2(14.3)	12 (85.7	
Metastasis			
Yes	5(16.1)	26 (83.9)	0.734
No	5(11.9)	37 (88.1)	

DISCUSSION

There were 108 patients in this hospital-based retrospective study, with more female patients than males. The ratio of male to female was 1:1.12. The findings of this study were identical to those of a study conducted at the University of Texas in the United States of America, which found that male to female ratio was 1:1.2-1.5 [22].

The preponderance of the patients in this research were above the age of 50 years, with a median age of 59. The frequency of cholangiocarcinoma in both males and females is high in the sixth and seventh decades of life, according to a research by Mahajan *et al*., [23]. It was shown also that having old age (5th decade and more) was risk factor in developing cholangiocarcinoma [24]. The incidence of CCA, like other biliary tract cancers, increased with age, peaking between 55 and 75 years old, and is somewhat greater in

males than females, according to a research by Hoyos *et al*., [25].

In this study, all patients with cholangiocarcinoma had obstructive jaundice as a clinical feature. Bertani *et al*., found that perihilar CCA is the most common cause of bile blockage, which results in jaundice in patients [26].The findings were comparable to those of a research conducted in the United Kingdom by Shahid *et al*., In this study the perihilar location was the most prevalent location of cancer, accounting for 76 (71%) of the patients [27]. Similar findings were reported in the study done in USA by Maryland in John Hopkin whereby out of 294 of the patients with cholangiocarcinoma 196 (67%) had perihilar cholangiocarcinoma [28].

In half of the study participants, the tumor was found to metastasize on the adjacent organs. The most common organ of metastasis in 54 patients, 40 (74.1%) had liver metastasis. The similar findings was found in the study done by Wang *et al*., [29].

The most laboratory finding for cholangiocarcinoma tumor marker was CEA in 46 (42.6%) patients out of 108 who were checked with mean results of 52.53 ± 188.21 and 37 (34.3%) patients out of 108 were checked for CA 19-9 mean results of 668.08 ± 911.35 prior to treatment. Relatively, In clinical routine, CA19-9 represents the most widely used tumor marker in CCA patients, as well CEA showed a higher accuracy for the differentiation between CCA and patients with primary sclerosing cholangitis (PSC) [30]. These tumor markers were found to be elevated on these patients. The similar findings were found in study done in Jiaotong University and Luoyang Central Hospital revealed that the sensitivity of a CA19-9 value and a CEA value in diagnosing cholangiocarcinoma were 77.14% and 68.57%, respectively [31].

In this study it has showed that among 73 patients who were given treatment at MNH. 63 (86.3%) patients had no complication while 10 (13.7%) patients had complication where by peri-catheter leak after PTBD being 4 patients (40%). Similar findings were found by Gupta *et al*., [32], that showed majority of the patients had no early complication post intervention. In another study it was revealed that there were few complications of PTBD in patients who underwent treatment [33].

On the mortality post treatment it was showed 7 (9.6%) patients died within 30 days post treatment. 1 patient being post whipple`s procedure and others treated with palliative by-pass surgeries but died due to presenting with late stage of the cancer. Low mortality of the patients in 30 days may be due to non-surgical (PTBD) palliative management offered to them. This is explained by decrease of liver function test post intervention and hence alleviates the adverse symptoms. This was similar to the study done by Knap *et al.,* [34], which showed that 66 (90.4%) survived post interventions. It was also shown by the study done by Sapisochin *et al*., that survival after CCA management, in 1, 3, and 5-year survival rates can reach 93%, 84% and 65% respectively [35].

In this study showed there was no statistical significant association between factors associated with early treatment outcome as majority of patients about 86% had no complication after intervention. this findings mirrors the findings in the study done by Gupta *et al*., comparing the outcomes of patients with malignant hilar strictures and GBC undergoing unilateral or bilateral metallic stenting which showed no major complications were encountered after intervention [32].

Limitations

Since data were collected in a retrospective manner, the study subjected to incompleteness data from files and electronic records; which limited the inclusion of the data in the study. Some of the variables were assessed in a subjective manner since clinical complications documented in the records might have not been uniformly assessed between patients attended by the clinicians.

CONCLUSION

There were no statistical significant found in factors associated with early treatment outcome. A half of patients (50%) were presenting in advanced stage of disease and more than half (59.3%) were treated non-surgically (PTBD).

Abbreviations

ALP; alkaline phosphatase, ALT; alanine aminotransferase, AST; Aspartate transaminase, CA 19-9; carbohydrate antigen 19-9, CCA; cholangiocarcionoma, CEA; carcinoembryonic antigen, CT; computed tomography, MNH; Muhimbili National hospital, MRCP; Magnetic resonance cholangiopancreatography, PSC; primary sclerosing Cholangitis, PTBD; percutaneous transhepatic biliary drainage, SPSS; statistical package for social sciences.

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Author's Contributions

All listed authors participated in the development of the study design and the implementation strategy. Lukiza Julius Kamhabwa is the principal investigator who designed the study, performed the analysis, interpretation of data, report drafting and wrote the manuscript. Ally Mwanga, Victor Ngotta and Mabula Mchembe were co-investigators and involved in study design, proposal approval, and analysis, interpretation of

data and writing and approval of the manuscript. Timon Theophil Theonest participated in report review and publication. All authors participated in reviewing the manuscript up to the final version to be submitted.

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Availability of Data and Materials: The datasets used and/or analyzed during the current study are available from corresponding author on a reasonable request.

Ethical Consideration

Ethical clearance to carry out this study was sought from the Muhimbili University of Health and Allied Sciences (MUHAS) Institutional Review Board (IRB) and permission to conduct the study was requested from the MNH. A waiver of informed consent was requested from the IRB since data were collected retrospectively. The identity of the study participants were made anonymous by coding their identity.

Consent for Publication: Not applicable

Competing Interests: All authors declare no competing interests.

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