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Case Series

Surgery Section

Standardisation of Decision Making in Hilar Cholangiocarcinoma Management: A Case Series

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ABSTRACT

Hilar Cholangiocarcinoma (CCA) is a very complex disease that requires the best multidisciplinary decisions. Improved outcomes are reported only in high-volume centres with good expertise and the latest technology in radiology for imaging and intervention, endoscopy, and surgery. However, in India, only very few centres have very good infrastructure for the same. Additionally, protocol-driven treatment is also not uniform in India. To fulfil this gap, authors believe that a strict, disciplined work-up of these complex cases is the only way to achieve optimal treatment. Authors propose a protocolised checklist involving multidisciplinary decisions for hilar CCA patients that could be used. This case series aims to assess the oncological outcome of hilar CCA using our checklist and, secondarily, to assess the immediate postoperative outcome and complications in these patients. Out of 20 patients, 13 underwent successful hepatectomy based on the decisions made. No mortality was noted in this case series. Two cases had a postoperative liver failure (Clavien Dindo 3A). All 13 patients had an R0 resection. The mean length of the tumour-free margin was 8.46 mm. Doing two-dimensional surgical simulation preoperatively and adhering to the special plane of transection helped in attaining R0 resection. Here, a small series of hilar CCA is presented which was managed successfully, signifying the importance of a protocol-based approach which can be easily adapted and reproduced.

Keywords: Future liver remnant, Hilar stricture, Resection, Treatment protocol

INTRODUCTION

Hilar CCA is a very complex and rare disease that requires the best multidisciplinary decisions for its management [1,2]. Standardised appropriate use of the latest technology reflects their results. Protocol-driven treatment is not uniform in India [3-5].

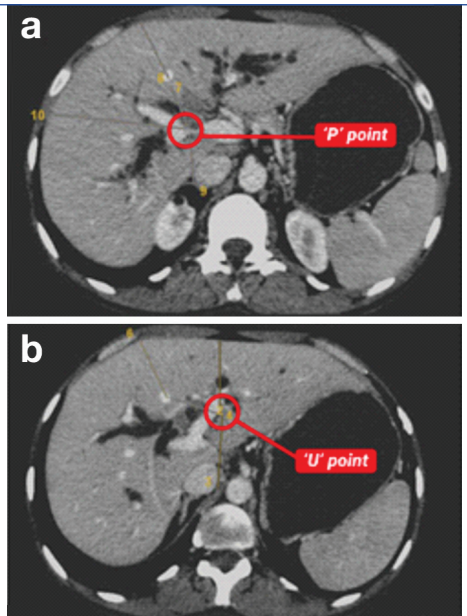
CASE SERIES

This case series was done on hilar CCA patients who were operated on between 01.10.2019 and 30.09.2020 over a period of one year at GEM Hospital and Research Centre, Coimbatore, Tamil Nadu, India. The minimum follow-up in this study was one year from the surgery date. The patients' clinicodemographic and perioperative details were collected and noted.

All patients underwent a 4-phase contrast-enhanced Computed Tomography (CT) scan. The longitudinal involvement of the malignant stricture based on the Bismuth-Corlette and Starzl Classification and the distal bile duct involvement were noted [6]. The latter would warrant additional pancreatoduodenectomy. Staging was based on the AJCC 8th edition [7]. Vascular involvement of the tumour was assessed in detail. Contact with a vessel alone may not be a sign of inoperability, but stenosis, occlusion, and contour irregularity would necessitate vessel resection or reconstruction.

The side of origin and involvement of the Segment 4 artery were specifically noted when Segment 4 is considered part of the Future Liver Remnant (FLR). Preservation of remnant outflow was ensured. The number of ducts at the transection line was also noted for accurate reconstruction planning. Anatomical variations were documented according to standard classifications as described by biliary variations according to Huang TL et al., arterial classification as per Michel NA, and portal vein anatomy noted according to Cheng S et al., classification [8-10].

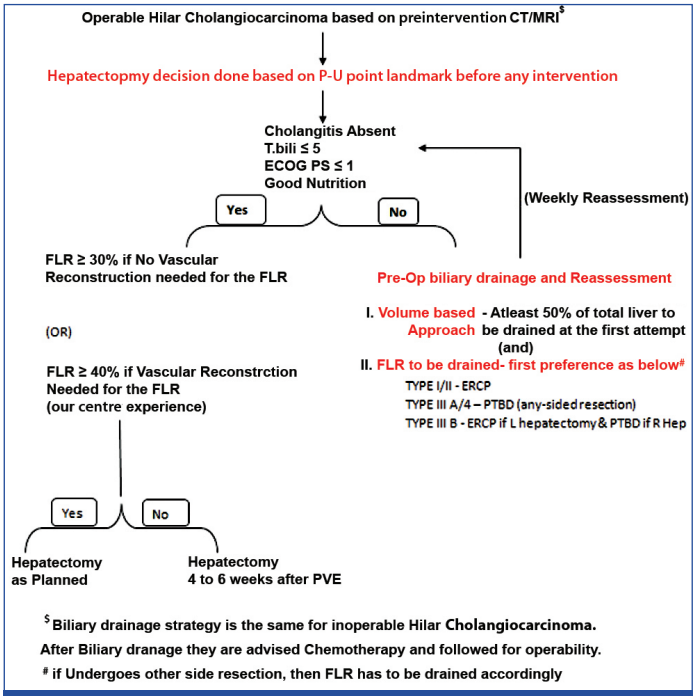
When planning the resection plane and plan of surgery, it was done with respect to the 'P' and 'U' points [11]. The 'P' point was where the right portal vein bifurcates, and the 'U' point denoted the level of origin of the umbilical portion of the left portal vein [Table/Fig-1]. In a left-predominant disease, if the tumour extent on the right bile duct was well before the medial/proximal part of the P point, a left hepatectomy with caudate resection would suffice. However, in a left-predominant disease, if the tumour on the right bile duct had crossed the medial/proximal part of the P point but well before the lateral/distal part of the P point, then a left extended hepatectomy is mandatory for oncological resection. For the same left-predominant disease, if the tumour had crossed the lateral/distal part of the P point also, then it was considered inoperable. The same criteria apply for a right-predominant disease, and decisions are based on the extent on the left side based on the U point [12].



[Table/Fig-1]: Planned planes of transection: a) Left and left extended hepatectomy with caudate lobe resection with P point as a landmark; b) Right and right extended hepatectomy with caudate lobe resection with U point as a landmark.

FLR was calculated both during primary planning and immediately preoperative time (post decompression of the bile ducts) to avoid over-calculation. The quality of the remnant liver in terms of Liver Attenuation Index (plus five or above) and lack of atrophy, and an FLR of 30% were ensured to avoid posthepatectomy liver failure. If there was suspicion of cirrhosis or fibrosis, a fibroscan was done. Magnetic Resonance Imaging (MRI) with Magnetic Resonance Cholangiopancreatography (MRCP) was used only as a secondary investigation when ductal involvement at the planned transection line was inconclusive with CT alone. A PET scan was done in patients with a CA19-9 level of more than 100, and staging laparoscopy was performed in all patients irrespective of CA19-9 level [13]. Tissue diagnosis was not routinely done at the centre, and treatment was based on imaging [14]. Brush cytology was done only when the patient was subjected to endoscopic biliary drainage.

Indications for preoperative biliary drainage included patients requiring right or extended right or extended left hepatectomy, patients with a total bilirubin level of more than 10 mg/dL, and those with an FLR less than 30% [15]. Except for left hepatectomy, all other surgeries were deferred until the serum bilirubin level was less than 5 mg/dL. Endoscopic Retrograde Cholangiopancreatography (ERCP) with a plastic stent was the primary method of drainage for type 2 and type 3B strictures. Percutaneous Transhepatic Biliary Drainage (PTBD) was preferred for type 4 and type 3A strictures, and long strictures on a case-by-case decisions as described in the flowchart [Table/Fig-2]. We ensured that at least 50 to 60% of the liver was drained in the first attempt to prevent the need for re-intervention, which could increase the chance of cholangitis [16]. Portal Vein Embolisation (PVE) was planned when the FLR was less than 30% [17].

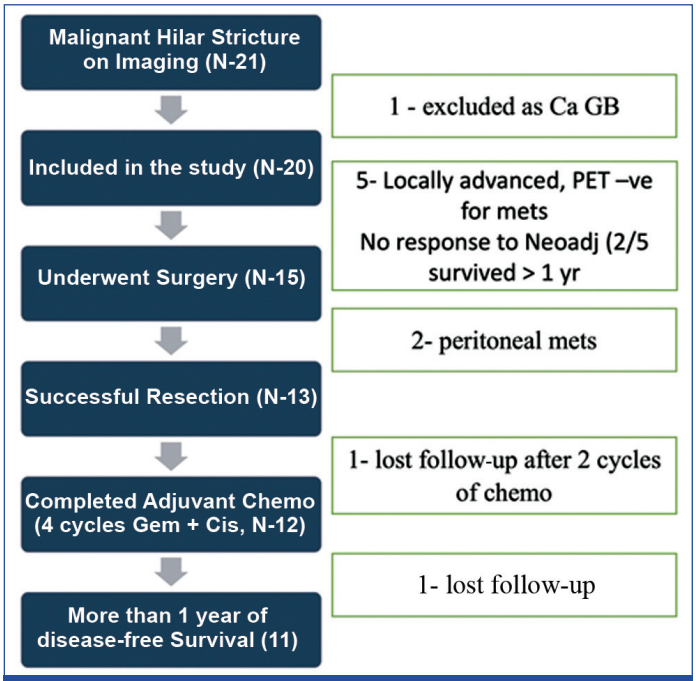


[Table/Fig-2]: Hilar Cholangiocarcinoma (CCA) flowchart.
PVE: Portal vein embolisation; FLR: Future liver remnant; ERCP: Endoscopic retrograde cholangiopancreatography; PTBD: Percutaneous transhepatic biliary drainage

All hepatectomies were done along the transection plane decided in the clinic's radiology meeting [18], with caudate excision and hepato-duodenal ligament lymphadenectomy [19]. Detailed records of the operative findings, postoperative complications, events, and the histopathology report of the final specimen biopsy were documented. The sample all-in-one proforma is enclosed in [Annexure-1], which contains the form for collecting patient's disease-related details, ranging from laboratory tests, radiological tests, histopathology, additional investigative modalities, intraoperative details, neoadjuvant and adjuvant treatments, follow-up, and an algorithm for managing the disease.

During the study period, about 21 hilar strictures were evaluated. All strictures were suggestive of a malignant cause based on imaging. One patient was excluded from the study as it was a case of gall bladder carcinoma with a hilar stricture. Therefore, 20 patients were included in the study. The median age at presentation was 62 years (Range: 51-69 years). Fifty percent of the patients had controlled diabetes mellitus and/or systemic hypertension. All patients had a good performance status with Eastern Cooperative Oncology Group Performance Status (ECOG PS) 1 or 2. The main presenting symptoms were jaundice and pruritus in 11 (55%) patients. Cholangitis was present in only 3 (15%) patients. Seven (35%) patients presented with weight loss and dyspeptic symptoms. The median Total bilirubin level during presentation was 7.6 mg/dL (Range: 1.8-15.2 mg/dL).

Five out of 20 patients (25%) were found to have locally advanced unresectable carcinoma with no evidence of metastasis [Table/Fig-3]. These patients underwent four cycles of neoadjuvant chemotherapy with Gemcitabine and Cisplatin, but none showed a significant response to the chemotherapy. Two out of the five unresectable patients survived for more than a year. Fifteen (75%) patients underwent diagnostic laparoscopy, and two patients were found to have peritoneal metastasis (13.3%). Although CA 19-9 levels were measured in all patients, no correlation was found with the aggressive nature of the disease, as only one of the two patients with peritoneal metastases had a CA 19-9 more than 100. Finally, thirteen (86.66%) patients underwent successful resection.



[Table/Fig-3]: Flow chart of the case series.

As the diagnosis was based on imaging, only 2 out of 15 patients underwent brush cytology during the placement of an endoscopic stent for preoperative biliary drainage. Thirteen out of 15 patients were operated on without preoperative tissue diagnosis, and their resected specimens revealed hilar CCA. Imaging was done before biliary drainage in 13 out of 15 patients, while two patients were referred after endoscopic stenting. PVE was not required in any of the cases in present series.

In two out of 15 patients who underwent surgery, left hepatectomy was done without preoperative biliary drainage. Thirteen patients underwent biliary decompression before surgery, with seven patients underwent ERCP with plastic stenting, four patients underwent PTBD, and two patients underwent multiple interventions in view of inadequate drainage.

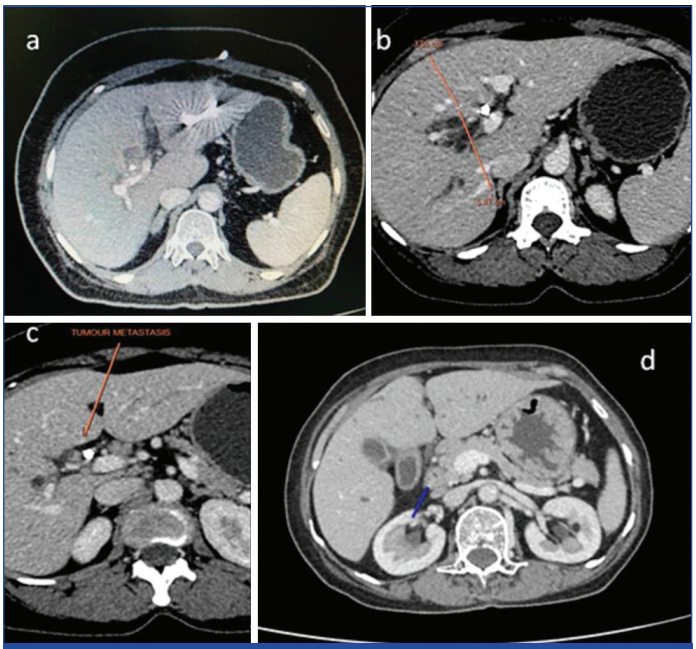
Hepatectomies performed for various types of hilar CCA, as guided by the Bismuth-Corlette and Starzl classification, are depicted in

[Table/Fig-4]. Out of a total of 13 hepatectomies, seven patients underwent right hepatectomy, and three patients underwent left hepatectomy, respectively. Notably, one patient with type IIIA Bismuth and IIIA Starzl hilar underwent left hepatectomy and a double duct anastomosis.

Bismuth Starzl	I	II	IIIA	IIIB	IV
I					
II		RH, RH			
IIIA			RH, LH		
IIIA+			RH, RH		
IIIB				LH	
IIIB+					
IVA			RH, RH, ERH		
IVB				LH	
V					ERH, ELH

[Table/Fig-4]: Distribution of hepatectomies for various types of Hilar CCA on the basis of Bismuth-Corlette and Starzl classification.
RH: Right hepatectomy; LH: Left hepatectomy; ERH: Extended right hepatectomy; ELH: Extended left hepatectomy

Even though there was a tumour involving the right secondary confluence, this was due to an anatomical variation where the right duct had an early bifurcation and the tumour extent on the right side was well before the P point. One patient underwent extended left hepatectomy, and two patients had extended right hepatectomy for extensive lesions [20]. Both Bismuth and Starzl classifications guided the type of surgical resection, but the final decision about the extent of resection was based on the transection plane with respect to the 'P' and 'U' points on CT imaging [Table/Fig-5]. No hepato-pancreatoduodenectomy was offered in any of the cases. Other intraoperative and postoperative findings are depicted in [Table/Fig-6] [21,22].



[Table/Fig-5]: a) Involvement of the left portal vein by tumour; b) Two separate ducts at the plane of transection; c) Intrahepatic metastasis at segment 4; d) Intrahepatic extension of tumour.

Pringle's maneuver was used in 10 patients and was done a maximum of six times, with a clamp time of 15 minutes each. No significant intraoperative events were noted. There was no relationship between the duration or number of Pringle's maneuvers done and the postoperative liver failure. Vascular reconstructions were not done in this study.

Postoperatively, the median hospital stay was 10 days (range: 5-20 days). The median POD-5 International Normalised Ratio (INR) was 1.4 (Range: 1.2-2.5). Two patients who underwent extended right hepatectomy developed posthepatectomy liver failure based on the 50-50 criteria. Both cases with posthepatectomy liver failure were of International Study Group of Liver Surgery (ISFLS) grade 2 [22]. These cases had a delayed recovery of the graft with prolonged biochemical coagulopathy and increased ascetic output. The FLR volume cut-off in the series was 30%.

Operative and postoperative findings	Observations
Median operating time (minutes)	520 (240-800)
Median blood loss (mL)	1000 (500-2000)
Biliary complications	1 (self-limiting cut surface leak)
Postoperative interventions	0
Postoperative liver failure	2 (Grade A- Managed conservatively) [21]
Postoperative complication- Clavin Dindo 3A or higher [22]	2
Median hospital stay (days)	10 (5-20)

[Table/Fig-6]: Other intraoperative and postoperative findings from the operated cases.

The histopathological details of the resected specimens from the 13 resected cases are shown in [Table/Fig-7].

Final histopathology-Key indicators	Distribution from 13 resected cases
Differentiation- G1 Well/G2 Moderate/G3 Poor	3/7/3
T1/T2/T3	3/5/5
R0 margins	13/13
Mean length of tumour free margin	8.46 mm*
Lymph node involvement (N1)	10/13
Lymph node harvested (> or =3)	12/13
Lymph vascular invasion	3/13
Peri neural invasion	4/13

[Table/Fig-7]: Final histopathology from resected cases with key indicators.
*while calculating the average, in the cases where two ducts were obtained- the lowest obtained margin was considered for calculation

The chemotherapy protocol followed in this series was Gemcitabine + Cisplatin for four weeks in the adjuvant setting and up to six cycles in the neoadjuvant setting [23]. During postoperative follow-up, 12 patients completed four cycles of adjuvant chemotherapy. Eleven patients were still surviving beyond six months postoperatively. Two patients who underwent successful resection were lost to follow-up. Surveillance imaging with triphasic CECT was done in 11 patients every six months, showing no evidence of recurrence.

DISCUSSION

The management of hilar CCA depends on optimal preoperative work-up, including ideal cross-sectional imaging and the utilisation of adjuncts like biliary drainage and PVE in appropriate patients for a better postoperative outcome. Because of the disease's complexity, a proforma was designed [Annexure-1] based on current evidence to standardise the decisions during the course of treatment.

This standardisation made the treatment noncompromised and cost-effective in the Indian setting. Although many risk factors like inflammatory bowel disease, primary sclerosing cholangitis, chronic viral hepatitis, hepatolithiasis, and cirrhosis have been proven to cause hilar CCA [1,2], despite investigating for common causes, the aetiology was not defined in most of the patients.

Preoperative imaging plays the most vital role in deciding the further course of management. CECT, MRI with MR angiogram, MRCP, and PET CT are the imaging options for hilar CCA [3,4]. CT as a single investigation gives us a roadmap of the radial extent of ductal and vascular involvement, the volume of FLR, and intrahepatic metastases. MR is time-consuming and FLR calculation was difficult [24]. PET CT could upstage a few patients, but unlike carcinoma of the gall bladder, metastases in hilar CCA were less common. Fusion CT done along with PET is mostly of low resolution requiring proper CT in addition. Present study preferred four-phase CECT

abdomen in the patients with MRCP only in selected patients. Only one patient in present study required MRCP in addition to CT for identifying longitudinal ductal extent in a type IIIA CCA with left lobe metastasis. Extended left hepatectomy was done in a patient to include metastasis also as MRCP gave us an idea of the long uninvolved right sectoral ducts available for hepatico-jejunostomy. There is no concrete evidence to date that intrahepatic oligo-metastasis is a contraindication for surgery in hilar CCA [25,26].

Imaging and surgical planning were done before the drainage procedure because the stent would decompress the biliary system and prevent us from defining the extent of the disease, and a few artifacts will hinder in planning the transection plane. CT has a superior ability to reveal tumour extensions longitudinally and radially in an undrained dilated bile duct. Instrumentation causes bile duct wall inflammation that is indistinguishable on imaging from tumour spread.

The surgical strategy was planned using two-dimensional (2D) surgical simulations incorporating a unique plane of transection of the liver for hilar CCA using CT reconstruction. Though various softwares have evolved to aid preoperative simulations, the proper utilisation of CT reconstruction achieves most of its prerequisites. Preoperative tissue diagnosis was not mandatory in this study, and only two patients who had brush cytology had undergone endoscopic biliary drainage elsewhere. Authors tried to limit the endoscopic interventions as the chance of septic complications was high [27].

Optimising the FLR was quintessential in hilar CCA, as most of the resectable cases require major hepatectomies. Two ways of facilitating the FLR were by improving its function with preoperative biliary drainage and increasing its volume by PVE [15,16,27]. According to Nagino M et al., regardless of the location of the biliary obstruction, percutaneous transhepatic, endoscopic, or surgical drainage can be used. However, such methods should be used that can be safely performed with the equipment and techniques available at each facility [16]. The selection of the drainage method was based on the side of the liver to be resected and the FLR. The initial drainage procedure should drain at least 60% (including the correction factor of nearly 10% of volume based on our software) of the total liver since the bilirubin should decrease as soon as possible [28]. ERCP or PTBD was based on the local experience, unlike some major centres that have moved towards naso-biliary drainage for hilar CCA [29,30]. Previous experience in the hospital showed that patients had higher infective complications with multiple ERCP stents and re-interventions. But recently in high-volume ERCP centers which do drainage for hilar CCA, the results are good [31].

Hence, PTBD was preferred whenever more than one system needs to be drained. This was done to prevent re-intervention attempts which would increase the chance of cholangitis [16,27]. Even though much literature argues about an increased incidence of tumour seeding with PTBD, few pieces of evidence are against that [32]. Tumour seeding can be avoided by keeping the PTBD catheters away from the stricture and avoiding re-intervention and manipulation of the tumour [33]. Although PVE increases the resectability of patients with hilar CCA [15], none of the operated patients in this study underwent PVE or vascular resections as FLR was adequate in view of case selection. The cut-off for FLR for this is variable at different centres and evolving with surgeons pushing toward lower volumes and excellent postoperative management [34].

Govil S et al., described that, although logic dictates that right-sided tumours (Bismuth-Corlette Stage IIIA) should be best treated by right hepatectomies, and left-sided tumours (Bismuth-Corlette Stage IIIB) by left hepatectomies, Left hepatectomies for PeriHilar Cholangiocarcinoma (PHC) may require Right Hepatic Artery (RHA) resection because of its intimate relationship with the biliary confluence [35]. Consequently, right hepatectomies are preferred for Bismuth-Corlette IIIB tumours. But safe extended resection with arterial reconstruction on the remnant side increases the ability to perform potentially curative Left hepatectomies for PHC.

This also improves the resectability rate for PHC, particularly for Bismuth-Corlette Type IV tumours by using arterial reconstructions of the FLR. The larger liver remnant after left extended/left hepatectomies results in less postoperative liver dysfunction and a shorter hospital stay without increased operating time, blood loss, or morbidity [6].

In this series, anatomical variation of the right bile duct with early bifurcation led to left hepatectomy even though it was a IIIA Bismuth stricture. The Starzl classification helped in subclassifying IIIA Bismuth into IIIA and IVA Starzl, thereby enabling accurate planning of right and right extended hepatectomy. The classical decision-making based on Bismuth-Corlette classification alone is not justified [5]. Authors decision was based on P and U points, the Starzl classification (extent of disease on the nondominant side), and the remnant volumes. We believe that one of the main reasons for a better R0 resection in present series was that the best of the four options was selected between right hepatectomy, extended right, left, and extended left hepatectomy. This selection was based on which surgical transection plane of the four surgeries would show radiological clearance of at least 1 cm along the longitudinal extent. Authors were able to determine all these factors based on the preoperative four-phase CT only. Even though present study results need to be validated over larger numbers, it is felt that the results at present are comparable or even better than some major series when the checklist is followed systematically [36,37].

Gemcitabine+Cisplatin was the standard chemotherapy protocol given in neoadjuvant, adjuvant, and palliative settings. Based on the ABC-02 trial and its follow-up, the combination of Cisplatin and Gemcitabine in the first-line setting remains the standard treatment for patients without targetable alterations [23].

CONCLUSION(S)

A multidisciplinary team approach brings optimal results in hilar CCA. Indian centres without referral and organ-based approaches have less volume, and standardisation is difficult. Authors presented a small series of successfully managed hilar CCA patients, underscoring the importance of a protocol-based approach. [Annexure-1]: Proforma attached separately.

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