

The impact of endoscopic biliary drainage on the nutritional status of patients with malignant perihilar or perampullary biliary strictures

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Abstract. *Background and aim:* Malignant biliary obstruction is the cause of complications affecting nutritional status. Biliary drainage with stenting is the recommended palliative treatment for these patients. This study assesses the impact of biliary drainage on nutritional status by comparing patients before and after the procedure. *Methods:* This study evaluates, through a retrospective analysis, the variation in patients nutritional status before and after biliary drainage whether in perihilar or perampullary strictures. We studied 200 patients with tumoral biliary stricture who underwent endoscopic biliary drainage. Demographic, anthropometric and clinical data were collected before and after drainage in two stages (1 and 3 months). Statistical analysis was performed using SPSS26 software. *Results:* The results showed a significant increase in mean weight, reaching 59.27kg after 3 months ($p<0.05$). Mean BMI also increased significantly, (20.39kg/m² after 3 months ($p<0.05$)). NRI decreased significantly after drainage. 35.17% still had severe undernutrition after 3 months ($p<0.05$). Mean ALB increased significantly, (34.52g/l after 3 months ($p<0.05$)). Mean BT also decreased significantly, (15.03mg/l after 3 months ($p<0.05$)). However, the decrease in CRP was not statistically significant. The WHO performance score showed significant improvement, with 25% of patients presenting with Stage 0 after 3 months. Pruritus and jaundice were absent in 100% of patients after 3 months. When comparing the perihilar and perampullary stenosis groups, no significant differences were observed for any of the parameters studied. *Conclusions:* The results suggest that endoscopic biliary drainage significantly improves the nutritional and clinical status of these patients, irrespective of the location of the obstruction. (www.actabiomedica.it)

Key words: perihilar, perampullary, biliary stricture, endoscopic biliary drainage, nutritional status.

Introduction

Malignant stenoses can occur in any segment of the biliary tree (1). They may be due to pancreatic cancer, biliary tract cancer, gallbladder cancer or metastases (2). Depending on the location of the tumor, the stenosis may be perihilar or perampullary. The perihilar type begins in the bile ducts just outside the liver. Perampullary compression refers to a stenosis around the ampulla of Vater (3). Clinically, these

strictures present with jaundice, most often associated with pruritus, with angiocholitis evolution, accompanied by severe malnutrition, weight loss, anorexia and pain, leading to a reduced quality of life (4). The best potentially curative treatment for malignant biliary obstruction is complete surgical resection (5,6), but unfortunately the majority of these patients with advanced stages are not good candidates for such curative treatment and can only benefit from palliative therapy (7,8). Drainage with stenting is the reference

treatment in such cases. This treatment is now considered a major component of best supportive care for malignant biliary strictures (9,10). Its aim is to remove the biliary obstacle in order to reduce cholestasis and its associated morbidities and improve their quality of life. The median survival of these patients is more often poor but its way better after drainage (11). The aim of this study was to evaluate, through a retrospective analysis, the variation in nutritional status before and after biliary drainage, according to the perihilar or periampullary obstruction over two different periods.

Materials and Methods

Data acquisition

This retrospective study was carried out at the Ibn Sina University Hospital in Rabat, Morocco, where the records of 200 patients with biliary stenosis of tumoral origin (perihilar or periampullary) who underwent successful endoscopic biliary drainage with biliary prosthesis placement between January 2015 and March 2019 were identified. We included in this study all adult patients aged 18 years and older, with a diagnosis of malignant biliary stricture confirmed by Imaging and/or histopathology, and who have availability of clinical, anthropometric and biological data before and after drainage. We excluded all patients with biliary stenosis of benign origin, patients who had undergone recent biliary surgery, patients with associated pathology altering nutritional status (liver failure, renal failure, chronic inflammatory disease...) as well as patients with failed endoscopic biliary drainage. The diagnosis of malignant biliary stenosis was established by a set of diagnostic tests, including clinical examinations, biological analyses (notably markers of cholestasis such as total bilirubin) and radiological investigations, such as abdominal ultrasound and cholangiography by magnetic resonance imaging (MRI) or endoscopy (ERCP - endoscopic retrograde cholangiopancreatography). Confirmation of the diagnosis was based on identification of the stenosis in the bile ducts, with histopathological confirmation in cases where a biopsy was performed. Study analysis was limited to patients

treated up to March 2019. This period was chosen due to the availability of clinical and biological data in the Ibn Sina Hospital registry, as well as the end of data collection for clinical research at this date. After March 2019, a reorganization of hospital resources and data management processes took place, making continued data collection for the study difficult. In addition, the time limit made it possible to maintain consistent and rigorous follow-up of patients within 3 months of drainage, thus guaranteeing data quality and relevance. For each patient we recorded age, sex, type of obstruction (perihilar or periampullary), anthropometric parameters (Weight (kg), Height (m), BMI (kg/m^2)), biological parameters (Albumin (ALB g/l), C-reactive protein (CRP mg/l), Total bilirubin (BT mg/l)). Protein-calorie malnutrition was assessed by the nutritional risk index (NRI) calculated using the following equation:

$$\text{NRI} = (1.519 \times \text{Albumin g/l}) \times (0.417 \times (\text{Current weight}) / (\text{Normal weight})) \times 100.$$

A patient is considered severely malnourished if the $\text{NRI} \leq 83.5$, moderately malnourished if the NRI is between 83.5 and 97.5, and normal if the $\text{NRI} \geq 97.5$. As well as all clinical parameters, namely the WHO performance score divided into 6 stages, ranging from 0 (normal state of health) to 4 (complete disability), pruritus, jaundice and frequency of vomiting (daily, occasional, absent). All these parameters were sampled before drainage and after drainage at two different times: after 1 month and after 3 months.

Statistical analysis

Statistical analyses were performed using SPSS software (Statistical Package For Social Sciences version 26.0), quantitative variables were described using mean and standard deviation, categorical variables were described using numbers and percentages. The paired t-test was used to assess pre- and post-drainage changes in nutritional status. To compare differences between the mean values of two groups, the independent samples t-test was used. A P value of less than 0.05 was considered statistically significant.

Results

Patients' characteristics (Table 1).

Nutritional status pre- and post-drainage

The results of the nutritional status assessment are presented in Table 2. During the follow-up period, of the 200 patients, 12% died after 1 month of drainage and 27.5% after 3 months of drainage (Figure 1).

Clinical assessment pre- and post-drainage

The analysis of clinical parameters is presented in Table 3.

Results of nutritional assessment by site of obstruction

Comparison of nutritional status and biological parameters for the perihilar and periampullary groups are presented in Table 4. Comparison between the perihilar and periampullary groups showed a slight difference between the nutritional assessment and clinical

parameters of the two groups, which was not statistically significant ($p>0.05$).

Discussion

Malignant biliary strictures are diseases with a poor prognosis and a low survival rate. Their rapid progression and late diagnosis mean that palliative treatment is often indicated (12). Malignant biliary strictures of prehilary or periampullary origin lead to obstruction of the bile ducts, causing cholestasis, lipid malabsorption and altered nutritional status (13). Endoscopic biliary drainage, including metal or plastic stenting, is a key intervention for restoring bile flow and improving patients' quality of life (14). However, its impact on nutritional rehabilitation remains an under-explored topic. In contrast to most studies, which focus solely on the technical parameters of biliary drainage (efficacy of deobstruction, complications, survival), our work specifically evaluates the evolution of nutritional status before and after endoscopic biliary drainage, integrating anthropometric parameters (Weight, BMI), clinical markers (WHO, Pruritus, Jaundice, Vomiting), biological markers (BLT, CRP, ALB) and a validated nutritional score (NRI). To our knowledge, this is the first study to focus on the assessment of nutritional status in these patients before and after endoscopic biliary drainage in two stages (after 1 and 3 months), demonstrating the relationship between restoration of bile flow and improvement in nutritional status. A disturbance in bile flow leads to a rapid increase in bilirubin, reflecting the severity of the cholestasis. CRP, a systemic inflammatory marker, rises to high levels in cases of angiocholitis or associated systemic inflammation, while albumin levels fall due to nutrient malabsorption and chronic inflammation (15). Evaluation of these parameters in our patients prior to drainage confirms the effect of this disturbance, since mean BLT levels reached 200.72 mg/l and CRP=61.73 mg/l, while ALB averaged 29g/l. The nutritional status of these patients is closely linked to disturbances in these biological parameters. Elevated total bilirubin, a direct marker of biliary obstruction, is associated with lipid and fat-soluble vitamin malabsorption (A, D, E, K),

Table 1. Patients' Characteristics

	Mean (SD) or %
Gender	
Men	51%
Woman	49%
Age (years)	59.68±13.69
Site of obstruction	
Perihilar	45.5%
Periampullary	54.5%
Drainage type	
Biliary drainage	85.5%
Duodenal drainage	4%
Bilio-digestive Endoscopic Ultrasound-Guided Biliary drainage (EUS-BD)	10.5%
Type of prosthesis	
Metal prosthesis	77%
Plastic prosthesis	23%

Table 2. Comparison of pre- and post-drainage nutritional evaluation parameters

	BEFORE DRAINAGE	1 MONTH AFTER DRAINAGE		3 MONTHS AFTER DRAINAGE	
	Mean (SD) or %	Mean (SD) or %	<i>P value</i>	Mean (SD) or %	<i>P value</i>
WHO score • STAGE 0 • STAGE 1 • STAGE 2 • STAGE 3	4.1% 43.2% 52.1% 0.6%	14.4% 53.2% 24.3% 3.6%	<i>0.000</i>	25% 53.6% 17.9% 8.1%	<i>0.000</i>
WEIGHT (Kg)	56.95 kg (±9.83)	57 kg (±10.11)		59.27 kg (±10.14)	
BMI Kg/m²	19.63 kg/ m ² (±3.42)	19.66kg/m ² (±3.40)		20.39 kg/m ² (±3.46)	
NRI • Normal nutrition • Moderate undernutrition • Severe undernutrition	0 (0%) 70 (35%) 130 (65%)	12 (6.84%) 86 (48.86%) 78 (44.31%)		25 (17.24%) 79 (54.48%) 41 (35.17%)	
ALBUMIN (ALB)	29 g/l (±4.31)	32 g/l (±5.48)	<i>0.000</i>	34.52 g/l (±4.5)	<i>0.000</i>
TOTAL BILIRUBIN (TB)	200.72 mg/l (±105.94)	32.82 mg/l (±34.3)	<i>0.000</i>	15.03 mg/l (±23.96)	<i>0.000</i>
C-REACTIVE PROTEIN (CRP)	61.73 mg/l	57.1 mg/l	<i>0.89</i>	56 mg/l	<i>0.80</i>

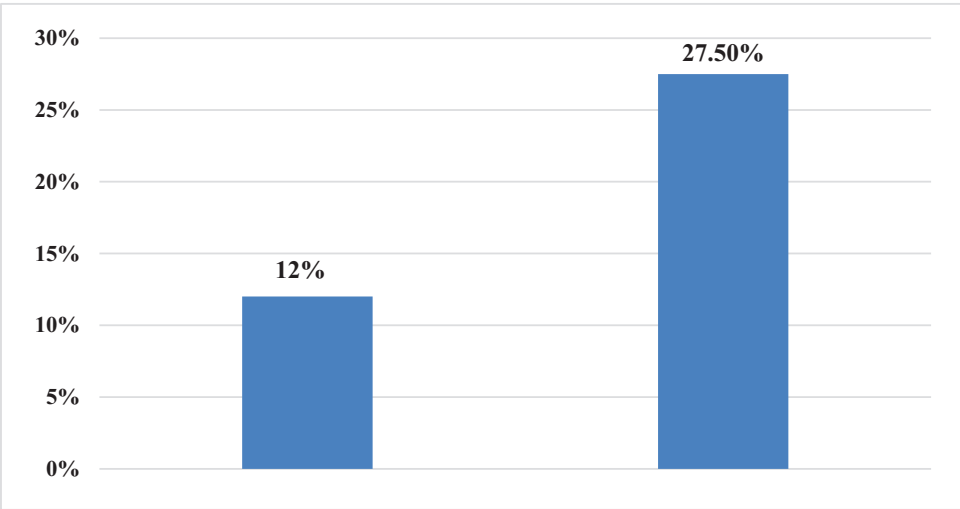


Figure 1. Percentage of deaths after endoscopic biliary drainage

contributing to undernutrition (13). Elevated CRP aggravates protein catabolism and contributes to tumor genesis (16). ALB synthesized by the liver is a late but crucial nutritional marker: its level decreases under the combined effect of reduced hepatic synthesis, digestive

losses and intake deficiency (15). Assessment of the nutritional status of our sample showed a deterioration in the latter, with an average weight of 56.95kg and an average BMI of 19.63kg/m². Calculation of the nutritional risk index (NRI) showed that 65% were

Table 3. Comparison of pre- and post-drainage clinical evaluation parameters

	BEFORE DRAINAGE	1 MONTH AFTER DRAINAGE		3 MONTHS AFTER DRAINAGE	
	Percentage	Percentage	<i>P value</i>	Percentage	<i>P value</i>
WHO					
• STAGE 0	4.1%	14.4%	<i>0.000</i>	25%	<i>0.000</i>
• STAGE 1	43.2%	53.2%		53.6%	
• STAGE 2	52.1%	24.3%		17.9%	
• STAGE 3	0.6%	3.6%		8.1%	
Pruritus					
• Yes	92%	1.8%	<i>0.000</i>	0%	<i>0.000</i>
• No	8%	98.2%		100%	
Jaundice					
• Yes	84.5%	1.7%	<i>0.000</i>	0%	<i>0.000</i>
• No	15.5%	98.3%		100%	
Vomiting					
• Dailies	18%	0.9%	<i>0.000</i>	0%	<i>0.000</i>
• Occasional	65%	10%		9.6%	
• Absent	17%	89.1%		90%	

Table 4. Comparison of pre- and post-drainage nutritional status of perihilar and periampullary groups

	BEFORE DRAINAGE		AFTER 1 MONTH OF DRAINAGE			AFTER 3 MONTHS OF DRAINAGE		
	Perihilaire Average or	Periampullary Average or	Perihilaire Average or	Periampullary Average (±SD) or% (±SD)	<i>P</i>	Perihilaire Average (±SD) or% (±SD)	Periampullary Average (±SD) or% (±SD)	<i>P</i>
Weight	56.65	57.01	57.37	57.27	<i>0.07</i>	60.51	58.16	<i>0.2</i>
BMI	19.64	19.53	19.69	19.63	<i>0.15</i>	20	19.91	<i>0.8</i>
NRI								
• Severe undernutrition	88.31%	82.35%	45.05%	54.61%	<i>0.21</i>	25.27%	31.48%	<i>0.5</i>
• Moderate undernutrition	11.68%	17.64%	47.2%	44.4%		58.24%	60.18%	
• Normal	0%	0%	7.69%	0.9%		16.48%	8.33%	
ALBUMINE	29.31	29.25	32.18	32.25	<i>0.9</i>	34.74	34.29	<i>0.6</i>
TOTAL BILIRUBIN	219.29	184.5	37.44	29	<i>0.2</i>	17.62	13.04	<i>0.2</i>
C-REACTIVE PROTEIN	62.82	60.61	37.64	35.38	<i>0.2</i>	45.42	30.75	<i>0.6</i>

severely malnourished. These biological disturbances also determine clinical symptomatology: jaundice (70-90% of cases) follows the evolution of bilirubinaemia, while pruritus (50-70%) is aggravated by inflammation (17). These results concur with those obtained

in our study, since 84% of our patients had jaundice and 92% pruritus before endoscopic biliary drainage. Vomiting, linked to cholestasis and nutritional deficiencies, and impaired performance index (WHO STAGE 2 in 52.1% of cases) reflect the severity of undernutrition

and systemic inflammation. Analysis of nutritional and biological parameters after endoscopic biliary drainage reveals promising results. Evaluation of anthropometric parameters, namely weight and body mass index, showed a significant improvement in both after 1 and 3 months of drainage. Weight increased from a mean of 56.95 kg before drainage to 59.27 kg after 3 months of drainage ($p < 0.05$) and BMI increased from 19.63 kg/m² before drainage to 20.39 kg/m² at 3 months of drainage ($p < 0.05$). The improvement in these two parameters led to a change in the nutritional status of these patients, as the study of protein-calorie malnutrition using the Nutritional Risk Index (NRI) showed that patients with severe undernutrition showed only 35.17% after 3 months of drainage, compared with 65% before drainage. And 17% of patients no longer showed any signs of undernutrition. The results obtained for the biological parameters showed an improvement across the board. Albumin increased significantly at 1 and 3 months after drainage ($p < 0.05$), reaching 34.52 g/l after 3 months ($p < 0.05$), compared with 29 g/l pre-drainage, in line with the results obtained by Peiryan et al, who observed a significant rise in albumin levels after one month of drainage (18). In their study, Zakosek et al. used the PNI (prognostic nutritional index) score to assess the nutritional status and survival of their patients (19). The serum albumin level in the PNI is an indicator of nutritional status. Low albumin levels are associated with malnutrition and weight loss, which have a negative impact on the survival and recovery of cancer patients and after possible chemotherapy. Therefore, for the above reasons, a low NIP value will correlate with unfavorable survival in cancer patients. (19) A meta-analysis of 11 studies of pancreatic cancer patients showed that a low PNI value was significantly correlated with poorer overall survival (20). Cui et al. reported that PNI was an independent predictor of survival in patients with advanced hilar cholangiocarcinoma (18). Bilirubin levels improved remarkably, with drainage inducing a reduction in BLT levels of over 50% after 1 month of drainage, from an average of 200.75 mg/l to 32.82 mg/l after 1 month of drainage ($p < 0.05$). In the study by Sayeed et al, the efficacy of biliary drainage was demonstrated by a significant reduction in bilirubin levels, from 13 mg/dL at baseline to 1.3 mg/dL (IQR: 0.9-2.1)

after four weeks (21). This reduction, in line with previous studies such as that by Robson et al (22), confirms the role of biliary decompression in relieving symptoms and underlines its palliative efficacy in malignant obstruction (21, 22). C-reactive protein showed an improvement after drainage, but this was not statistically significant ($p < 0.05$). CRP fell from 61.73 mg/l before drainage to 57.1 mg/l after 1 month, then to 56 mg/l after 3 months of drainage. This explains why the drop in CRP levels after drainage is not maintained over time, which is in line with the results obtained by Francisco J Padillo et al, who observed an immediate drop in CRP levels after restoration of bile flow, but which gradually disappeared over time (23). Evaluation of clinical parameters showed a clear improvement in all factors, namely performance index, jaundice, pruritus and vomiting. This improvement was mainly due to the reduction in bilirubin levels following biliary tract clearance. This was also demonstrated in the study by Sayeed et al (21), who found relief from pruritus, as assessed by the VASP, with a significant improvement in scores from 7 at baseline to 6 after one week ($p = 0.007$) and to 5 after four weeks ($p = 0.001$). These results reinforce the efficacy of biliary decompression in relieving pruritus-related distress, in line with studies by Robson et al (22), Barkay et al (24) and Salman-roghani et al (25). Once all these parameters had been assessed, a comparison was made between the perihilar and perampullary groups. The results revealed a slight difference between these two groups, which was not statistically significant. ($p < 0.05$) for all parameters.

Conclusion

This study shows that endoscopic biliary drainage significantly improves the nutritional status of patients with perihiliary or perampullary malignant biliary strictures. These results underline the importance of endoscopic biliary drainage in improving the nutritional status and quality of life of patients with malignant biliary strictures.

Ethic Committee: This is a retrospective non-interventional study exempt from the requirement for ethics approval

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article.

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