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Placement of metallic biliary endoprostheses in complex hilar tumours

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KEYWORDS
Percutaneous biliary drainage;
Hilar cholangiocarcinoma;
Hilar tumour;
Endoprosthesis;
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Abstract
Purpose: To assess the technical success, clinical success and complications after 1 month of percutaneous biliary drainage with the placement of several metallic endoprostheses in complex hilar liver tumours.
Materials and methods: This is a retrospective study, on a homogenous target population of 68 consecutive patients, who underwent multiple percutaneous biliary drainage for complex hilar tumour (Bismuth type II, III and IV) between August 1998 and August 2010. Patients benefiting from previous endoscopic drainage were excluded from the study. The clinical data, biological data, imaging and interventional radiology procedures were studied.
Results: The rate of success of the technique was 98.5% and the clinical rate of success was 84% after 1 week and 93% after 1 month. The rate of minor and major complications was 25 and 13% respectively.
Conclusion: Multiple percutaneous biliary drainage in complex hilar tumour is a safe and effective first intention procedure.

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Cholangiocarcinoma and hepatic metastases are the main causes of the obstruction of the hepatic hilum. These tumours have a poor prognosis with a mean survival of 5 years for cholangiocarcinomas under 5% [1]. Most of these patients die less than one year after the diagnosis of cholangiocarcinoma [2]. The locoregional tumoral invasion and the alteration of the patient's general state often prevent curative surgical treatment [3,4]. Palliative treatments are therefore the only ones proposed [5]. Drainage of the bile ducts, whether surgical, endoscopic or percutaneous, has become an indispensable palliative treatment [6,7]. Although carried out for many years, consensus still has not been reached about the rules of biliary drainage, in particular for complex hilar tumours (Bismuth type II, III and IV). Certain teams drain the maximum dilated biliary sectors, others consider that draining 30% of the liver suffices to provide a significant improvement in the jaundice [8–12]. The purpose of this retrospective study is to present the results of a series of extensive percutaneous biliary drainages with the placement of several endoprostheses in cases of complex hilar tumours (Bismuth type II, III and IV).

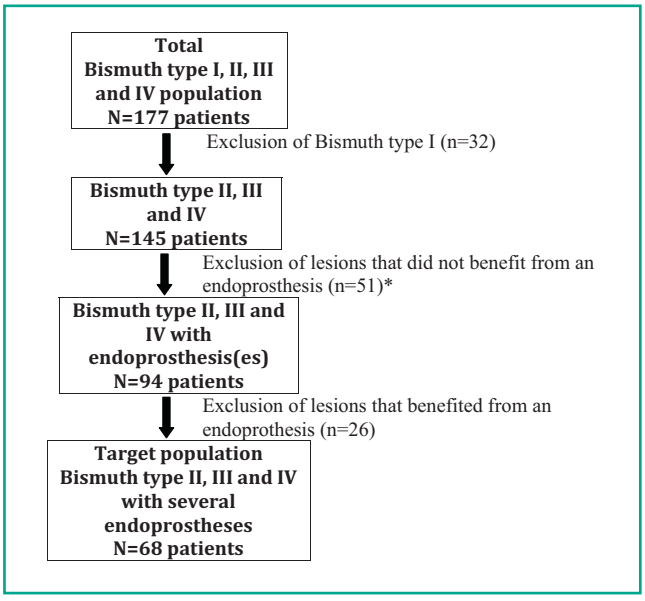

Figure 1. Selection of the target population for the study. *These patients underwent surgery or benefited from external biliary drainage.

Materials and methods

This retrospective study selected all consecutive patients that underwent biliary drainage for a malignant obstruction of the hepatic hilum between August 1998 and August 2010 for a total of 177 patients. Patients benefiting from previous endoscopic drainage were excluded from the study. The indication of biliary drainage was first raised following multidisciplinary consultation. The consent of all patients was obtained after being informed as to the therapeutic procedure, its indications, results and possible complications. The clinical data, biological data, imaging and interventional radiology procedures were studied retrospectively.

The population

All 177 patients benefited from an assessment of the imaging, most often comprising abdominal sonography, a thoracoabdomino-pelvic CT and a hepatic MRI. The locoregional assessment was used to classify the extension of the biliary cholangiocarcinoma according to the Bismuth and Corlette classification and plan the subsequent interventional treatment [3]. This classification was also used by extension for the secondary invasion of the hilus. A common therapeutic strategy of drainage was used by the interventional radiologists of the department. Therefore, in case of biliary drainage of a hilar tumour, each excluded and dilated biliary sector had to be drained and, if possible, fitted with an endoprosthesis in the absence of atrophy or major invasion of the tumour on a sector or a lobe of the liver. A strict selection provided a target population of 68 patients who benefited from biliary drainage with the placement of several endoprostheses for complex hilar tumour (Fig. 1). None of these patients were candidates for curative surgical treatment due to the extension of the tumour and/or the performance status of the patient. The different histological types of tumours, the ASA score, the symptoms of the patients before the drainage as well as the clinical and biological monitoring during the month following the drainage was obtained in the 68 patients.

Procedures

The drainages, by five different hospital practitioners during the period examined, were all carried out under a general anaesthetic. The patients had adapted antibioprophylaxis by a third generation cephalosporin such as cefazolin before any procedure. All of the patients were treated in an intervention room after control of the haemostasis assessment. The number of biliary sectors was first defined according to the Bismuth classification, the trophicity of the dilated biliary sectors and the hepatic tumour invasion from the data obtained from the CT, MRI and sonograph.

First, a dilated intrahepatic duct was detected under sonography control in order to be able to puncture it with a thin needle such as a Chiba 15 cm long, 21 or 22 G (gauges). A percutaneous transhepatic cholangiography was then carried out in order to allow for the precise analysis of the anatomy of the biliary tree and an exact classification of the hilar tumour [13]. The cholangiography confirmed the planning of the drainage procedure by choosing the biliary sectors to fit.

Then, at the same time as the Chiba needle, a splenoportography needle was introduced under scopy to insert a hydrophilic guide such as the Térumo 0,035F (French) in the bile ducts of the sector approached. Several incisions were required in order to place the number of biliary prostheses previously defined. The operator then crossed the biliary obstructions with the 7F guide catheter in all of the biliary sectors approached. After crossing the obstruction, an angioplasty balloon dilated the obstruction and facilitated the placement of the self-expanding uncovered metallic endoprosthesis (Fig. 2).

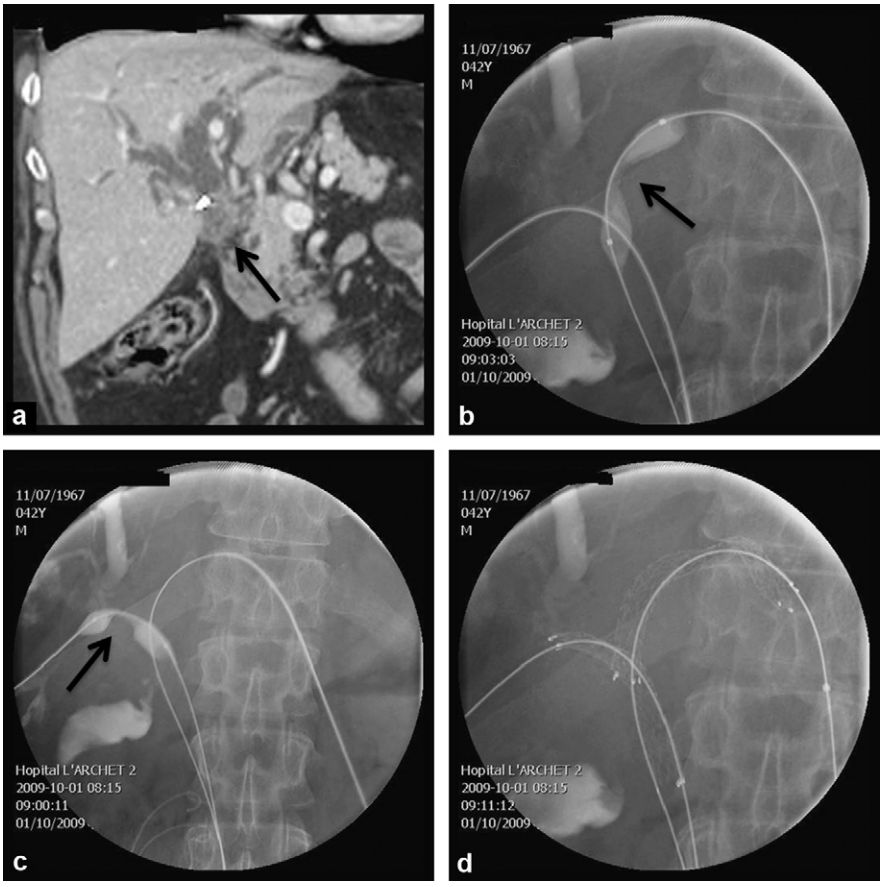

Figure 2. Biliary drainage with the placement of two endoprostheses for a Bismuth type II hilar cholangiocarcinoma: a: CT at portal vein in coronal section revealing a tissue lesion (arrow) centred on the primary biliary convergence; b and c: dilation with an angioplasty balloon 10 mm × 4 cm of obstruction at the two common bile ducts. The obstruction is detected by the impression made during the dilation (arrows); d: placement of prostheses by guidewire delivery at the previously detected obstructions. Result after opening of both prostheses.

In case of the initial non-crossing of one of the obstructions, an external 8F drain was placed upstream from the uncrossed obstruction. Temporary internal/external drains were placed at the level of the obstructions crossed. The patient was then seen 3 to 4 days later for another attempt to cross the obstruction and place the prosthesis. The final placement of the prostheses opposite the obstructions was controlled at the end of the procedure by cholangiography. It was used to see the passage of the contrast product at the duodenum without residual obstruction on the bile ducts, attesting to the good cover of the obstructions. The placement of the endoprostheses was always protected by an internal-external biliary drain, which was removed on D2 after controlling the good permeability of the prostheses (Fig. 3).

Definitions

The success of the technique was defined by the placement of endoprostheses according to the therapeutic project with respect to the obstructions with a good final passage of contrast product in the digestive tract during the final cholangiography. For this study, in accordance with the majority of publications, we defined clinical success as a reduction of 30% and more in the total bilirubin after 1 week or a reduction of 75% and more of the total bilirubin after 1 month, as measured in micromoles/L [14—16]. The complications were divided into major and minor complications according to the standards of the Society of Cardiovascular and Interventional Radiology [17]. Major complications included sepsis or post-therapeutic cholangitis, haemorrhages requiring a blood transfusion, abscess, peritonitis, cholecystitis, pancreatitis, pleuropneumonia and death. All other complications were considered to be minor, including minimal haemorrhages, biliovenous fistula, subcapsular biloma, stent migrations, etc. These minor complications did not involve prolonged hospitalisation. Cholangitis was defined by fever exceeding 38 °C associated with abdominal pain without any other identifiable seat of infection.

Statistical analysis

The data to calculate of the rate of success of the technique, the clinical success and the complications was registered by computer. These rates were expressed as a mean percentage. Two tests were used to search for the predictive factors of clinical success or failure of the biliary drainage. The Mann-Whitney-Wilcoxon test was used during the analysis with qualitative variables and Fisher's exact test during

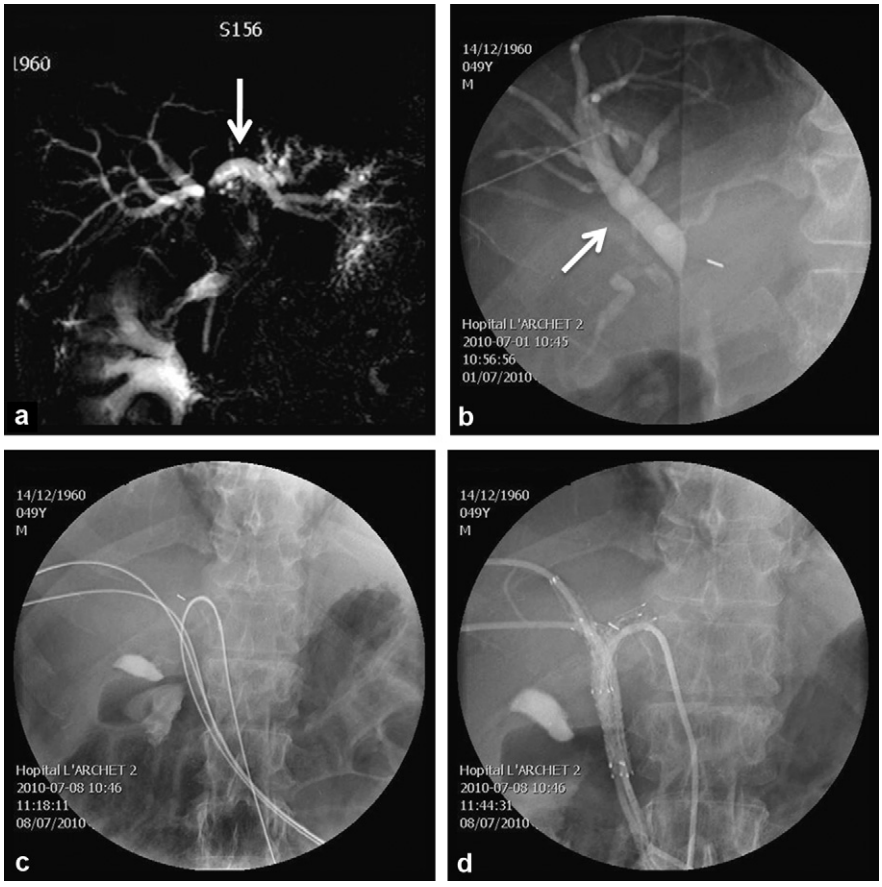

Figure 3. Biliary drainage of a Bismuth type III hilar cholangiocarcinoma: a: MRI with T2 weighting and 3D reconstruction confirming the dilation of the intrahepatic bile ducts (arrow); b: thin-needle cholangiography with major dilation of the bile ducts of the right para median sector that seems to be excluded from the other sectors; c: crossing three obstructions with three guides enabling the full drainage of the biliary tree; d: transitory protection for 48 hours of the incision after placement of endoprostheses by internal-external drains.

the analysis of the quantitative variables. The data was considered to be significant in case of $P \leq 0.05$.

Results

The population

The target population consisted of 42 men (62%) and 26 women (38%), a sex ratio of about 1.6/1. The mean age of the patients at the time of the diagnosis was 69 years (38—96 years). The mean ASA score was 2.3. All of the patients presented clinical jaundice and biological cholestasis with alteration of their general state and weight loss. Only three patients received care during an angiocholitis. The total pre-surgical bilirubin level oscillated between 29 and 927 μmol/L with a mean of 336.4 μmol/L (N < 17 μmol/L).

Aetiology and classification of hilar obstructions according to Bismuth

The causes of hilar obstruction were either cholangiocarcinomas ($n = 40$), or metastases ($n = 28$). The hilar obstruction was type II in 15 patients, type III in 25 patients, including 22 type IIIa and three IIIb, and type IV in 28 patients.

Success of the technique

The success rate for the technique was 98.5%. The only failure was complicated by the death of the patient following haemorrhagic shock before the placement of the endoprostheses. One hundred and thirty two procedures were carried out in the 67 patients, representing a mean of two procedures per patient. One hundred and sixty-one endoprostheses were placed with a minimum of two and a maximum of four prostheses.

Clinical success

Due to the retrospective nature of our study, a full biological assessment was not available for all of the patients in our population. Of the 50 patients, where 1 week of biological monitoring was available, 42 presented at least a 30% reduction in the total bilirubin, that is, a clinical success, of 84%. The reduction in the bilirubin varied from 34 to 88% with a mean of 59.5%. The assay of the total bilirubin was available after 1 month for 28 of the 50 previous patients. Twenty-six of these patients presented a reduction of over 75%, that is, a clinical success of 93% with reductions between 75% and 96% with a mean of 85.5%. Tables 1 and 2 present the variations in the rate of clinical success according to the aetiology of the tumour and

Table 1 Clinical success after 1 week according to the aetiology of the tumour and the Bismuth classification.

	Number of successes	Number of failures	Success rate (%)
Aetiology of the tumour ($n = 50$)			
CCK ($n = 31$)	26	5	84
Metastasis ($n = 19$)	16	3	84
Bismuth classification ($n = 50$)			
II ($n = 9$)	8	1	89
III ($n = 20$)	16	4	80
IV ($n = 21$)	18	3	86

CCK: cholangiocarcinoma.

Table 2 Clinical success after 1 month according to the aetiology of the tumour and the Bismuth classification.

	Number of successes	Number of failures	Success rate (%)
Aetiology of the tumour ($n = 28$)			
CCK ($n = 20$)	19	1	95
Metastasis ($n = 8$)	7	1	88
Bismuth classification ($n = 28$)			
II ($n = 5$)	4	1	80
III ($n = 11$)	10	1	90
IV ($n = 12$)	12	0	100

CCK: cholangiocarcinoma.

the Bismuth classification. Among the eight clinical failures after 1 week, four patients presented clinical success after 1 month. Among the four remaining clinical failures after 1 month, two died, the first from his cancer without an apparent link to the drainage, and the second from severe sepsis 1 week after the drainage. Among the two remaining patients in clinical failure after 1 month, we note one drop-out and one patient whose drainage reduced the bilirubin by less than 42%.

Predictive factors of failure

By analysing the different population characteristics, no predictive factors of clinical success or failure were detected.

Complications

The rate of minor complications was 25%. There were nine minor haemobilias, five bilomas, one prosthesis migration treated by the placement of another endoprosthesis, one biliocutaneous leak and one punctured subcutaneous haematoma. The rate of major complications was 13%. Three patients died: one from severe sepsis probably of biliary origin and two others from haemorrhagic shock with haemobilia and digestive haemorrhage. Two other patients presented a haemobilia requiring a transfusion and embolisation for one of them. One patient was treated for pneumopathy. One patient underwent surgery for cholecystitis 3 weeks after the placement of the endoprostheses. One patient presented acute kidney failure that cleared up under dialysis and finally, the last patient benefited from percutaneous drainage for a liver abscess.

Discussion

Biliary drainage with the placement of metallic endoprostheses has become a choice treatment for hilar tumoral obstructions [7]. In fact, due to the local aggressiveness of the tumour, these patients most often are not able to benefit from a curative treatment [18]. The technique of drainage with only one endoprosthesis in sub-hilar tumours or Bismuth type I hilar tumour is acknowledged. Bismuth type II, III and IV hilar tumours raise more questions due to its extension along the bile ducts. In these cases, biliary drainage of one sector, one lobe or the entire liver remains controversial. Our study tried to specify the success of the technique, the clinical success and describe the complications after 1 month of extensive biliary drainage with the placement of several endoprostheses in Bismuth type II, III and IV complex hilar tumours.

In our series, we isolated and privileged Bismuth type II, III and IV complex hilar tumours to discuss the value of the placement of several endoprostheses. The populations of the other studies published appear much more heterogeneous [11,12,15,19—22]. Endoscopic or percutaneous studies most often do not distinguish between patients

presenting obstructions due to Bismuth type II, III and IV complex hilar obstruction and Bismuth type I hilar and sub-hilar obstruction [20—22]. As far as we are aware, the literature on percutaneous drainage consists of a single recent study (2003) where the population is close to ours [11]. This publication is based on a population of 117 patients with a complex hilar tumour, including 61 that required bilateral biliary drainage. The other recent studies on percutaneous biliary drainage with the placement of several endoprostheses in hilar tumours only include 23 patients for another Inal study, 20 patients for Pappas, 19 patients for D'alincourt and six patients for Brountzos [12,20—22]. In addition, as opposed to these studies, our series presents a high percentage (78%) of Bismuth type III and IV hilar tumours that are, by definition, the most difficult lesions to drain. This percentage is 66 in the 2003 Inal study [20]. The heterogeneity is the same in the endoscopic drainage series. In the studies by De Palma and Chang, 54 and 29 patients presenting a Bismuth type II or III hilar tumour benefited from the placement of two endoprostheses [15,19]. Patients presenting a Bismuth type IV tumour were not treated in these two studies. The other recent studies include 23 and 30 patients with Bismuth type II, III and IV obstacles [16,23]. Finally, one study on 85 patients presenting Bismuth type III and IV hilar tumour compared endoscopic and percutaneous drainage [24]. Surprisingly, the drainage technique and the number of endoprostheses placed are not indicated in this study. Therefore, our study, compared with other recent studies, presents a homogenous and large target population. It is of further value since it specifically studies the drainage with the placement of several endoprostheses in Bismuth type II, III and IV tumours. In fact, in addition to a heterogeneous population, the other studies mentioned above also present an imprecise drainage strategy concerning the number of endoprostheses chosen or placed. These factors account for the difficulty comparing the results of our study with that of the existing literature.

The rate of success of the technique is high in our series (98.5%). This high rate of success is mainly due to the experience of the different operators and appears similar to the other recent percutaneous studies since all of these studies claim a 100% success rate [11,12,20—22]. This high rate should be considered since biliary drainage may involve several procedures, as is the case for 78% of our patients. In fact, the first procedure does not always cross all obstructions due to the major dilation of the intrahepatic bile ducts, associated with the hard and fibrous nature of the obstruction. A second procedure is then required. Eighty-three percent of our patients only required one or two procedures to totalise the drainage. The recent endoscopic series also had high rates of success of the technique, ranging from 73 to 100%. These results are often not as good as those of the percutaneous series, in particular for the bilateral drainage with a rate of 76.9% for De Palma and 90% for Naitoh in 78 patients and 29 patients respectively. These rates drop to 66% and 87% if only Bismuth type II, III and IV cholangiocarcinoma are taken into account [15,16]. Rerknimitr presents a 100% rate of success with the bilateral drainage of complex hilar tumours although on a small population of 30 patients [23]. The superiority of the percutaneous series in biliary drainage with the placement of several endoprostheses is largely due to the easier accessibility of the intrahepatic bile ducts by transhepatic approach than by endoscopy. During endoscopic biliary drainage, the endoprostheses are placed under scopic control after retrograde cholangiography. The cholangiogramme obtained is sometimes incomplete since the contrast product is stopped by the complete obstruction. The placement of the endoprostheses then becomes more random as concerns the choice of biliary sectors to fit. In case of radiological drainage, the percutaneous approach under sonographic control of the bile ducts associated with the analysis of the MRI data and the CT imaging enable the most complete direct cholangiography possible. The planning of the procedure thereby seems to be better.

Although the biological data is not available on the 68 patients in our series, the rate of clinical success after 1 week and 1 month are high (84% and 93% respectively). These rates are similar, whether they involve primary or secondary tumours and also whatever the Bismuth classification. These results are not found in the other series of percutaneous drainage. In these series, the rate of clinical success deteriorates for Bismuth type III and IV tumour. Therefore, in the 2003 study by Inal et al., the success rate decreases from 100% in case of Bismuth type I or II tumour, to 95% in case of Bismuth type III tumour and 66% in case of Bismuth type IV tumour [11]. In the other 2003 Inal study, the finding is similar with a clinical rate of success of 90% when including hilar and sub-hilar tumours, 82% in case of Bismuth type II, III and IV tumours and 71% in case of Bismuth type III and IV tumours [20]. The rate of clinical success in recent endoscopic series is not as good, in particular for Bismuth III and IV hilar tumours with a rate ranging from 73 to 100% [15,16,19,23]. The rate of success in series with selection criteria closest to ours is 73% and 77.3%. Paik has a clinical rate of success of 77.3% in a population of 44 patients presenting Bismuth type III or IV hilar tumour and De Palma has a rate of success of 73% for the bilateral drainage of 78 hilar tumours including 54 Bismuth type II and III hilar tumours and 24 Bismuth type I tumour [15,24]. This difference in the clinical rate of success between the series of percutaneous and endoscopic biliary drainage, like the rate of success of the technique, is due to the easier access to the intrahepatic bile ducts by percutaneous route. Therefore, in the percutaneous biliary drainages, in case of Bismuth type III or IV hilar tumours, it is possible to drain three biliary sectors in order to obtain the most complete biliary drainage possible. This was the case for 19 of our patients. With endoscopic drainage, it is only rarely possible, with experienced operators, to drain more than two sectors [25].

Cholangitis, haemobilia and biliary leaks are early complications most often encountered with percutaneous biliary drainage [20]. The overall rate of complications in our series is 38% with 25% minor complications and 13% major complications. This rate is similar that of the endoscopic or percutaneous series treating the same type of population. In fact, the studies by Inal, Paik and De Palma indicate an overall rate of complications of 29%, 31.7%, 29.5% and 26.9% [11,15,24]. Our complications are closely related to the number of procedures, the number of approaches and the Bismuth classification. The overall rate of complications increases with an increase in the number of procedures, the number of approaches and the Bismuth classification. The ASA score does not influence, as could be expected, the rate of complications. Nevertheless, these results are

predictable since the number of approaches and the number of procedures attest to the difficulty in drainage. Drainages with the lowest number of procedures and approaches limit the number of complications. Moreover, Inal already demonstrated that, if possible, it is preferable to place the endoprostheses directly without preliminary biliary drainage in order to minimise complications [20]. Eighty-four percent of our target population benefited from one or two procedures for the biliary drainage, thereby limiting the risks related to surgical procedures.

This study presents several biases and imperfections. First, due to the retrospective nature of the study, biological data is not available on all of the patients. Some data has been lost or never recorded. Some patients have dropped-out and we do not know whether the drainage was a clinical success or failure. Since the radiology department at Hôpital l'Archet is a regional reference centre for percutaneous biliary drainage, some of the patients treated only were hospitalised for 48 h before being sent back to their original department. After 48 h, these patients presented a decrease in the total bilirubin. Nevertheless, it remained under 30%. Second, this series on percutaneous biliary drainage with the placement of several endoprostheses should have been compared with a series of percutaneous drainages with the placement of a single endoprosthesis in a prospective control study. However, this type of study is difficult to carry out due to the relative rarity of malignant hilar tumours. Third, in this study we did not try to detail the medium and long-term permeability of the prostheses. It is therefore not possible to specify whether or not multiple stenting is a factor that increases or decreases the long-term permeability of endoprostheses. Nevertheless, we know that the mean duration of permeability of metal stents is approximately the same as the mean life expectancy of patients presenting malignant bile duct obstruction [9]. Another bias is due to the chose of biliary sectors to drain. The therapeutic strategy in our study was to avoid draining atrophied hepatic sectors or those presenting major invasion by the tumour. This choice was subjective and depended on the operators and was not based on an objective analysis, in particular by hepatic volumetry.

Conclusion

With a rate of success of the technique of almost 100% and a clinical success rate of about 90%, our series on multiple percutaneous biliary drainage in complex hilar tumours appear more effective than the series of endoscopic or percutaneous drainage recently published treating the same type of population. As opposed to these studies, the biliary drainage of a Bismuth type IV hilar tumour appears as effective as that of a Bismuth type II tumour. The rate of major complications of 13% in our series appears to be fully acceptable in view of the fragility of our population consisting of over 75% Bismuth type III and IV tumour with a mean age of 69 years and a mean ASA score of 2.3. Therefore, we consider that the most complete percutaneous biliary drainage possible with the placement of several endoprostheses should be proposed in first intention. However, a randomised prospective study comparing partial biliary drainage with total biliary drainage on the same type of population seems to be necessary in order to back up our results.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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