Result and cost of hepatic chemoembolisation with drug eluting beads in 21 patients

L. Vadot\textsuperscript{a,\*}, M. Boulin\textsuperscript{a,b}, C. Malbranche\textsuperscript{a}, B. Guiu\textsuperscript{c,d}, S. Aho\textsuperscript{e}, A. Musat\textsuperscript{f}, C. Pernot\textsuperscript{a}, M.H. Guignard\textsuperscript{a}, P. Hillon\textsuperscript{d,g}, F. Fagnoni\textsuperscript{a,b}

\textsuperscript{a} Pôle Pharmacie, CHU de Dijon, Bocage Central, 14, rue Gaffarel, 21000 Dijon, France
\textsuperscript{b} EA Inserm 4184, Université de Bourgogne, 7, boulevard Jeanne-d’Arc, 21000 Dijon, France
\textsuperscript{c} Department of Radiology, CHU de Dijon, Bocage Central, 14, rue Gaffarel, 21000 Dijon, France
\textsuperscript{d} Inserm U866, Université de Bourgogne, 7, boulevard Jeanne-d’Arc, 21000 Dijon, France
\textsuperscript{e} Department of Hospital Hygiene and Epidemiology, CHU de Dijon, Hôpital d’Enfants, 14, rue Gaffarel, 21000 Dijon, France
\textsuperscript{f} Medical Information Department, CHU de Dijon, Bocage Central, 14, rue Gaffarel, 21000 Dijon, France
\textsuperscript{g} Department of Hepatogastroenterology, CHU de Dijon, Bocage Central, 14, rue Gaffarel, 21000 Dijon, France

\textbf{KEYWORDS}
Hepatocellular carcinoma; Transarterial chemoembolisation; Drug eluting beads; Result; Cost

\textbf{Abstract}

\textbf{Purpose:} The aim of our study was to assess the results and cost of a treatment strategy involving transarterial chemoembolisation with drug eluting beads (DEB-TACE) in patients with unresectable non-metastatic hepatocellular carcinoma (HCC).

\textbf{Patients and methods:} This study included all patients treated with DEB-TACE in our hospital between January 2009 and December 2010. All patients received DEB-TACE on demand and were evaluated after each session.

\textbf{Results:} Twenty-one patients received an average of 1.3 sessions. The median time to treatment discontinuation and median progression-free survival was 181 days and 295 days, respectively. Toxicity caused treatment discontinuation in three patients (14%). For the hospital, the average direct cost of treatment was €6,033 according to the analytical accounting system vs. €4,558 according to the official tariffs from the new French Diagnosis-Related Group prospective payment system (P = 0.002).

\textbf{Conclusion:} In the treatment of HCC, on-demand DEB-TACE stabilises the disease in some patients but has not yet been thoroughly evaluated.

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\* Corresponding author.

\textit{E-mail address: lucievadot.ph@gmail.com} (L. Vadot).

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Abbreviations

AA  analytical accounting
AFP  alpha foetoprotein
BCLC  Barcelona Clinic Liver Cancer
TACE  transarterial chemoembolisation
BDMP  blood-derived medicinal products
CR  complete response
CU  care unit
DEB-TACE  drug eluting bead transarterial chemoembolisation
EASL  European Association for Study of the Liver
EXH  daily supplement for extra-long hospital stays
DRG  diagnosis-related group (basic medical/economic classification category)
GHS  groupe homogène de séjours (tariffs from the new French Diagnosis-Related Group)
HCC  hepatocellular carcinoma
HCV  hepatitis C virus
HGE  hepatogastroenterology
ICS  daily intensive care supplement
LBP  labile blood products
MRI  magnetic resonance imaging
NASH  non-alcoholic steatohepatitis
NCI-CTC  AE National Cancer Institute Common Toxicity Criteria for Adverse Events
PFS  progression-free survival
PR  partial response
SD  standard deviation
SMD  sterile medical devices
T2A  tarification à l’activité (national per-stay prospective payment system)

Introduction

With about 700,000 deaths in 2008, HCC is the third leading cause worldwide of mortality from cancer [1]. Seventy per cent of patients are diagnosed at an advanced stage and can no longer benefit from curative treatment (surgical resection, liver transplantation, percutaneous ablation) [2]. TACE is the treatment recommended in patients with an unresectable, non-metastatic HCC who are in a good general condition with preserved hepatic function (intermediate stage B of the BCLC classification) [2]. TACE relies on both local provision of the anticancer agent and on the dual arterial and venous supply to the liver making it possible to temporarily interrupt arterial flow without inducing ischaemic necrosis of the organ. Two randomised phase III trials and two meta-analyses have demonstrated that TACE increases survival in patients with unresectable, non-metastatic HCC, compared with intravenous chemotherapy and supportive care [3–6]. Even though TACE has been practised throughout the world for many years, the technique is still very heterogeneous, and depends on the centres and radiologists in charge of the procedure for the choice of anticancer agents, the doses, the vectors, the embolisation agents, the perfusion procedures and the frequency of the courses [7]. This heterogeneous management probably explains why a recent meta-analysis failed to conclude that TACE was superior to symptomatic treatment in patients with HCC [8].

Since 2006, new medical devices, drug-eluting beads (DEB), have been used as the vector for anticancer agents for TACE of HCC. These expensive devices have the twin advantages of reducing the systemic release of the anticancer agent by releasing it in a controlled way on contact with the tumour and of embolising the vessels supplying the hypervascularised nodules. These two advantages are still theoretical in as far as the only randomised study published, which compared the efficacy and tolerance of TACE with doxorubicin-eluting beads with conventional TACE using lipiodol as the vector, did not demonstrate any significant difference in terms of efficacy at 6 months between the two techniques [9]. Moreover, only one economic study compared the cost of DEB-TACE with conventional TACE, but it only provided information on the costs of the first course [10]. The aim of our work was to evaluate the result and overall cost of a treatment strategy in patients with unresectable, non-metastatic HCC using DEB-TACE.

Patients and methods

Patients

Our retrospective study included all the patients with HCC in whom treatment by DEB-TACE had been initiated in our hospital between 1st January 2009 and 31st December 2010. The indication for treatment with DEB-TACE was systematically determined during the weekly multidisciplinary digestive oncology consultation meetings in the presence of at least a radiologist, a gastroenterologist, a liver surgeon, a radiotherapist and an oncologist. The patients presented unresectable, non-metastatic, uni- or pachifocal (less than or equal to three nodules) HCC according to the EASL criteria, with preserved hepatic function (Child A or B7), satisfactory renal function (serum creatinine level less than or equal to 1.5 times the upper limit of normal), a left ventricular ejection fraction of more than 50% and no vascular contraindications to TACE [11].

Treatment

The DEB-TACE strategy adopted was on demand. The patients received one course and were retreated depending on their response to the first course, and so on after each course. The later courses were given every 2 months. The treatment was discontinued in the event of toxicity that contraindicated its resumption, if the patient refused it, if imaging showed progression or if the response allowed simple monitoring or curative treatment (resection, liver transplantation, percutaneous ablation). The DEB-TACE procedure took place in the interventional radiology room of the Department of Radiology of our hospital, according to a standard protocol. Following femoral catheterisation and complete vascular exploration (evaluation of the hepatic vascularisation and the accessory vascularisation), the radiologist injected the loaded beads within 20 minutes, by intra-arterial injection into the right or left branch of the hepatic artery, whichever supplied the greater part of the tumoral mass, as selectively as possible, and sometimes

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extremely selectively by using a Progreat™ 2.7 Fr microcatheter (reference MC-PP27131, coaxial with an integrated guide, Terumo, Guyancourt, France). At each session, the patients received a fixed dose of 50 mg of doxorubicin (Doxorubicin® 2 mg/ml, Teva, Paris, France) irrespective of their weight or height. Doxorubicin was loaded into 25 mg of eluting beads (HepaSphere™, Biosphere Medical, Roissy, France) in our hospital pharmacy. The solution with the DEB was presented in a 60 ml syringe. Before injection, the interventional radiologist added 20 ml of iodoxanol (Visipaque® 270 mg I/ml, GE Healthcare, Velizy, France) from a three-way tap, simply inverting the syringe to make a uniform mixture. The total volume theoretically injected to make the patient was 45 ml. Prophylaxis with ceftriaxone (Rocephine®, Roche, Neuilly, France) 1 g/d for 5 days starting on the day of the TACE procedure was systematic, in the absence of any known allergy.

The response to treatment was assessed by MRI or CT scan with contrast injection, according to the EASL criteria, 6 weeks after each course [11]. Definitions of the responses were: CR, disappearance of the target lesions (absence of contrast uptake in the arterial phase); PR, reduction of more than 50% in the size of the viable target lesions; progression, increase of more than 25% in the size of the viable target lesions or appearance of new lesions; stabilisation of the disease in all other cases. Toxicity was evaluated following each course according to the NCI-CTC AE version 3.0.

Economic analysis

The economic analysis was conducted from a hospital point of view from the first course of DEB-TACE with loaded beads until treatment discontinuation. For each patient, we identified all the stays and counted the number of days of hospitalisation related to the overall management of their HCC and all the resources consumed during these different stays.

Periods of hospitalisation took into account patients’ stays in the different units visited that is to say, stays in the HGE unit for administration of DEB-TACE and stays in other units for the treatment of toxicity related to this particular TACE treatment. Consultations and imaging sessions were not included. The main direct medical resources consumed by patients during their various stays were identified from the patients’ hospitalisation files or from nominative data recorded by the pharmacy. They included the SMD (microspheres and microcatheter), the medicinal products financed in addition to the tariffs of the new French Diagnosis-Related Group (DRG) payment system, labile blood products (LBP) and blood-derived medicinal products (BDMP). The costly medicinal products financed in addition to the GHS tariffs were identified from the list fixed by the ministerial decree of 4th April 2005 and updated [12]. The costs were evaluated by two costing methods: Analytical Accounting (AA) used in our hospital and the national GHS tariff of the TZA activity-based costing system (national per-stay prospective payment system). The overall hospitalisation costs according to the AA of our hospital included all the partial costs of hospitalisation of each CU visited by the patient during the management of his/her HCC. The partial cost corresponded to the running costs of the care units (CUs) in which each patient was hospitalised (net direct charges, medical/technical costs, food and accommodation and logistics costs). This excluded pharmaceutical expenditure (SMD, medicines financed in addition to the GHS, LBP and BDMP) of the CUs concerned, for which the cost of products actually consumed was recorded patient by patient. Resources were cost from unit prices obtained in 2009 and 2010 when calls for tenders were issued and contracts negotiated for medicinal products, and, according to the tariffs published in the Official Journal in 2009 and 2010 for LBP distributed by the Établissement Français du Sang [13]. The price of a vial of 25 mg HepaSphere™ was €526 including tax in 2009 and €693 including tax in 2010. The price of the embolisation microcatheter (Progreat™ 2.7 Fr, reference MC-PP27131 with integrated guide) was €365 including tax in 2009 and 2010. In order to evaluate the cost according to the national GHS tariffs, each extremely long stay was recorded as the number of days of hospitalisation exceeding the “upper limit” set for each GHS [14]. Each hospitalisation period included only one of the incomplete days of hospitalisation (the day of admission counted as a complete day whereas the day of discharge was not counted). The number of days of hospitalisation was established for each stay. This valuation method used the TZA remuneration rates, i.e. the hospitalisation tariffs for 2009 and 2010 fixed by ministerial decree for each GHS. The unique medical/economic classification of patients (DRG) assigned to each of these hospital stays was provided by our hospital’s Medical Information Department. Three different versions of the DRG classification were used (versions V10c, V11 and V11c) depending on the date of inclusion of the patients [15–17]. The GHS tariffs were fixed by the ministerial decree in force for the year concerned [18–20]. Any EXH, ICS supplements and the cost of expensive molecules (units used × unit price) were taken into account.

Statistical analysis

Means are presented with their ± SD. Frequency was compared using the Chi-squared test or the Fisher exact test. Means were compared using the Kruskal-Wallis non-parametric test. The time to treatment failure was defined as the time between the date of the first course of DEB-TACE and the date treatment was discontinued for any reason (toxicity, refusal by the patient, progression, death). Patients who underwent curative treatment were excluded from the date of the curative treatment. Progression-free survival (PFS) was defined as the time between the date of the first course of DEB-TACE and the date of progression. The survival curve was plotted using the Kaplan-Meier method. Statistical analysis used the STATA® program version 11 (StataCorp, Texas, USA). The significance level was set at P = 0.05.

Results

Baseline characteristics of the patients

Twenty-one patients (17 men and four women) were included in our study. The patients were between 55 and 88 years old with a mean of 72 years of age. Eighty-six per cent of these patients presented Child A cirrhosis. In the
The majority of patients (67%), the aetiology of the cirrhosis was alcoholic or alcohol/metabolic. The median number of nodules was 1 (mean 1.7 ± 1.1) with a median total tumour size for all nodules of 55 mm. The baseline characteristics of the patients are given in Table 1.

### Table 1 Baseline characteristics of the patients.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
<th>Median</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>74</td>
<td>72 ± 9</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17 (81)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>4 (19)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aetiology of the HCC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol + NASH</td>
<td>10 (47)</td>
<td>1.7 ± 1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Alcohol</td>
<td>4 (19)</td>
<td>55 ± 41</td>
<td>1.4</td>
</tr>
<tr>
<td>HCV</td>
<td>3 (14)</td>
<td>55 ± 41</td>
<td>1.4</td>
</tr>
<tr>
<td>NASH</td>
<td>2 (10)</td>
<td>55 ± 41</td>
<td>1.4</td>
</tr>
<tr>
<td>Healthy liver</td>
<td>2 (10)</td>
<td>55 ± 41</td>
<td>1.4</td>
</tr>
<tr>
<td>Prior treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (19)</td>
<td>55 ± 41</td>
<td>1.4</td>
</tr>
<tr>
<td>No</td>
<td>17 (81)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of nodules</td>
<td>1</td>
<td>1.7 ± 1.0</td>
<td>1.0</td>
</tr>
<tr>
<td>Size of the largest nodule (mm)</td>
<td>46</td>
<td>55 ± 41</td>
<td>1.4</td>
</tr>
<tr>
<td>Total tumour size (mm)</td>
<td>55</td>
<td>68 ± 41</td>
<td>1.4</td>
</tr>
<tr>
<td>Unilobar HCC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15 (71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>6 (29)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AFP (µg/l)</td>
<td>5</td>
<td>103 ± 261</td>
<td></td>
</tr>
<tr>
<td>Performance status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>15 (71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>6 (29)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>18 (86)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B7</td>
<td>3 (14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCLC score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>2 (10)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>13 (61)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>6 (29)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

AFP: alpha foetoprotein; BCLC: Barcelona Clinic Liver Cancer; NASH: non-alcoholic steatohepatitis; SD: standard deviation.

### Treatment

The patients received a mean of 1.3 courses. Sixteen patients (76%) had only one DEB-TACE course. Four patients (19%) had two courses and one patient (5%) alone had three courses. Seventeen patients (81%) received the whole dose of TACE (45 ml), four patients (19%) received at least two-thirds of the dose (more than 30 ml injected, i.e. more than 33 mg of doxorubicin). Three patients (14%) presented toxicity contraindicating continuation of the treatment while nine responding patients (43%) were simply monitored (n = 2) or received additional treatment (resection, n = 2; percutaneous ablation using radiofrequency or alcoholisation, n = 5).

The hepatic MRI slices from a patient considered a very good responder to DEB-TACE courses are shown in Fig. 1. The median time to treatment failure was 181 days. Our study concerned 33 hospital stays. The median stay for the first DEB-TACE was 4 days (mean 6 ± 5 days). The median duration of all the stays for patients receiving treatment by DEB-TACE was 7 days (mean 8 ± 7 days). After a mean follow-up of 337 days, ten patients (48%) were alive without progression. Median PFS was 295 days (Fig. 2). The PFS rate at 6 months was 75%. Three patients died from their HCC during the study period. Our study reported three grade 3−4 toxicities leading to treatment discontinuation for three patients (14%). They included a false aneurysm affecting the right superficial femoral artery and two oedematous ascitic decompensations. The patient with the vascular complication needed a surgical procedure: correction of the false aneurysm with lateral suturing of the superficial femoral artery. Other cases of toxicity observed mainly involved slight fevers, abdominal pain or grade 1−2 vomiting in ten patients (48%) in the 48 hours after DEB-TACE. The rise in hepatic enzymes remained moderate. No patient presented...

![Hepatic MRI of a patient treated with doxorubicin-eluting beads: a: before treatment; b: six weeks post-treatment showing complete necrosis.](image-url)
febrile neutropenia. No death was attributed to a complication of DEB-TACE.

Economic analysis

Table 2 presents the costs arising from one or more hospital stays resulting from the DEB-TACE strategy, according to both our hospital AA and to the national GHS hospitalisation tariff. None of the patients in our study received medicinal products financed in addition to the GHS, LBP or BDMP during their treatment. For the first course of DEB-TACE, the average direct medical hospital cost of treatment was €4265 according to our hospital AA vs. €2674 according to the national GHS tariffs (+€1591, P = 0.01). According to the AA, the direct medical hospital costs of an overall DEB-TACE strategy was on average €6033 vs. €4558 according to the national GHS tariffs (+€1475, P = 0.002).

Discussion

To date, only one phase II randomised study has compared DEB-TACE with conventional TACE in patients with HCC; it did not show the superiority of DEB-TACE in terms of response rate at 6 months [9]. Other studies evaluating the efficacy and tolerance of DEB-TACE beyond 6 months have been published but they only tested regimens with courses repeated every 2 or 3 months [21–26]. Our study is thus the first to provide the result of a strategy using on-demand DEB-TACE in a French population of patients with unresectable, non-metastatic HCC. We have been applying an on-demand strategy with DEB-TACE in our hospital since these beads became available. In this strategy, the response obtained after a given course, evaluated 6 weeks later by MRI, determined whether the patient should be retreated or not by successive courses. At the present time, even though a strategy with repeated courses of TACE appears to maximize the antitumour activity, it has not been proved to be really more effective, whereas it is more toxic. A panel of HCC experts has recently recommended an on-demand strategy for conventional TACE, but did not give any opinion on DEB-TACE [27]. Our study showed a median PFS of approximately 10 months in patients with unresectable, non-metastatic HCC treated with on-demand DEB-TACE. This seems to be comparable with the median PFS reported in the latest randomised TACE trial, which tested DEB-TACE against embolisation alone in patients with HCC [25]. In this trial, median PFS for patients in the group receiving DEB-TACE was 12 months; the patients received courses every 2 months with a maximum of three courses. In terms of tolerance, even though no patient died of complications resulting from DEB-TACE, 14% of them discontinued treatment due to severe toxicity. In the Precision V study, 13% of patients stopped treatment with DEB-TACE because of severe toxicity [9]. DEB-TACE is not free of therapeutic risk; the rate of treatment discontinuation due to toxicity is comparable with the rates observed for conventional TACE, i.e. 15 to 20% [7]. Very recently, a study compared the frequency of severe hepatic and/or biliary toxicity depending on the type of TACE (lipiodol or drug eluting beads) in a series of 208 patients treated for HCC or an endocrine tumour. In the 476 sessions of TACE received by the patients, severe hepatic and/or biliary toxicity as defined by the authors occurred after 82 sessions (17%). In multivariate analysis, the fact of having received DEB-TACE was significantly associated with severe hepatic and/or biliary toxicity (OR 6.6; P < 0.001) [28]. However, this toxicity was more frequently associated with the treatment of an endocrine tumour (non-cirrhotic liver) than with HCC. In addition the patients with an endocrine tumour had received a less selective treatment than the patients with HCC. The lower selectivity of DEB-TACE could thus explain the hepatic and/or biliary toxicity.

Eluting beads are innovative and costly medical devices. To date, only one study has considered the real cost of a first course of TACE with these devices [10]; our study is thus the first to evaluate the overall cost of treatment of HCC with DEB-TACE. AA accurately determines overall costs for treating HCC as regards the spending incurred by our hospital [29]. For a first course of DEB-TACE, the cost determined by AA was €4265 as against €3600 in a previous study [10];

Table 2 Mean costs of DEB-TACE treatment.

<table>
<thead>
<tr>
<th></th>
<th>Dijon University Hospitals AA</th>
<th>GHS hospitalisation tariffs</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (extremes)</td>
<td>Mean (extremes)</td>
<td></td>
</tr>
<tr>
<td>First course (€)</td>
<td>4265 (2449–13,833)</td>
<td>2674 (2092–5033)</td>
<td>0.01</td>
</tr>
<tr>
<td>Overall strategy (€)</td>
<td>6033 (2449–23,450)</td>
<td>4558 (2092–17,275)</td>
<td>0.002</td>
</tr>
</tbody>
</table>

AA: analytical accounting; GHS: groupe homogène de séjours (tariffs from the new French Diagnosis-Related Group).

Figure 2. Progression-free survival curve estimated by the Kaplan-Meier technique.
this cost difference may be explained by the small number of patients treated in the latter investigation (n=6). In our study, comparison of the tariffs assigned by the GHS with the AA of our hospital showed that the cost for managing a first course is statistically insufficient (P = 0.01). This difference has already been pointed out, but was not statistically significant in the earlier study [10] and illustrates the underestimation of innovative techniques by the national GHS tariff system.

Our study provides information on the overall cost of managing HCC with DEB-TACE until treatment is discontinued. We have taken into account the costs arising for all the courses of DEB-TACE as well as the costs arising from stays due to the toxicity of DEB-TACE courses. This evaluation provides information on the overall cost regarding benefits but also the risks of DEB-TACE. Our study showed that the overall care costs are not correctly assessed, since the real costs amounted to €6033 vs. €4558 allowed by the national tariff (P = 0.002). There are two possible reasons explaining this underestimate of costs. Firstly, the procedure has been coded without taking into account the technique used (DEB-TACE or conventional TACE) and is not classified as a separate act. The stays of two patients treated by different techniques were therefore classified in the same DRG. Secondly, three different DRG classifications were used during our study period. The V10c classification used before March 2009 had two levels of severity related to the patient’s comorbidities or advanced age; there are now four levels of severity in the V11 and modified V11 classifications for patients treated after March 2009. The impact of this classification has been shown for other pathological conditions [30].

**Conclusion**

In patients with unresectable non-metastatic HCC treated with on-demand DEB-TACE, we report a median PFS of 10 months and a 14% rate of treatment discontinuation for toxicity. The cost of overall management of an on-demand treatment strategy for HCC by DEB-TACE seems to be poorly valued by the T2A. This is probably due to the fact that no phase III study has proved the superiority of DEB-TACE over conventional TACE. In the context of the current system of hospital funding, it seems essential to carry out comparative medical/economic evaluations of DEB-TACE and conventional TACE strategies in patients with unresectable non-metastatic HCC.

**Disclosure of interest**

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

**References**


