Surgical management of malignant tumours invading the inferior vena cava

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Abstract

OBJECTIVES: The management of malignant tumours invading the inferior vena cava (IVC) generally requires a high-risk surgery with low long-term benefits. Surgical treatment with resection and/or embolectomy of the IVC may, however, be beneficial in selected patients. We describe our experience with regard to patient selection, operative technique and outcomes through a standardized and simplified approach.

METHODS: Between 1996 and 2012, 37 patients underwent extended resection of malignant tumours invading the IVC. Tumour infiltration was located at the hepatic and suprahepatic segment in 23 patients (62%), the renal segment in 6 (16%), and the infrarenal segment in 8 (24%). Fourteen patients (38%) had right heart involvement, of whom 5 had a tumour thrombus located in the pulmonary arteries (PA).

RESULTS: All the patients underwent a median laparotomy. A sternotomy with full liver mobilization was performed for tumours involving the PA, or the retrohepatic or supradiaphragmatic IVC. Cardiopulmonary bypass was performed in 15 patients (41%), with deep hypothermic circulatory arrest (DHCA) in 5 (14%). The 30-day mortality rate was 5.4%. The 1-, 5- and 10-year survival rates were 68.1, 45.7 and 40%, respectively, with a median survival of 18 months. Incomplete resection (R1 or R2) was the only parameter found to have a significant negative effect on survival (P = 0.003).

CONCLUSIONS: Radical resection of malignant tumours invading the IVC is feasible in carefully selected patients and may require CPB with or without DHCA. Morbidity and mortality are low and the survival rates acceptable, particularly in patients with complete resection of the tumour.

Keywords: Inferior vena cava • Malignant tumour • Strategy • Approach

INTRODUCTION

Malignant tumours involving the inferior vena cava (IVC) are either sarcomas arising directly from the vessel wall, or malignancies of other origins invading the IVC by direct endovascular extension and/or intraluminal thrombotic embolization [1]. Among these tumours, renal cell cancer (RCC) represents 85–90% of malignant kidney tumours and is often associated with IVC invasion (4–10% of all patients) [2]. In patients with RCC, involvement of the right atrium (RA) is encountered in 5–15% and pulmonary artery tumour emboli are more rarely observed [2–5]. In these cases, surgical intervention is considered the most appropriate treatment strategy [4], as conservative management consisting of chemotherapy and/or radiotherapy has not shown a clear beneficial effect on survival [2]. In fact, neoplastic extension of RCC into the IVC is not considered a negative prognostic factor [6, 7]. In the absence of perinephric fat or lymph nodal involvement, it has been observed that patients who undergo complete tumour excision with a radical nephrectomy and IVC thrombectomy have an overall and cancer-specific survival of 56.6 and 60.2%, respectively [8, 9]. Other malignant tumours that may invade the IVC include uterine leiomyoma, adrenocortical carcinoma, testicular carcinoma and liver carcinoma [10]. Primary leiomyosarcomas of the IVC have also been described, with ~300 cases reported in the world literature since 1871 [11].

Resection of tumours involving the IVC is challenging, and may require conventional cardiopulmonary bypass (CPB), with or without deep hypothermic circulatory arrest (DHCA). This is particularly the case in the presence of an intracardiac tumour component [12–15]. The aim of CPB and DHCA is to improve the safety and the efficacy of the surgical procedure, and to achieve a complete R0 resection. However, the surgical approach to the resection of tumours involving the retrohepatic portion of the IVC, the right heart chambers and/or the pulmonary arteries (PA) is not standardized. The aim of this retrospective study is to describe in...
detail our surgical approach to the resection of malignant tumours involving the IVC, and to report our outcomes.

MATERIALS AND METHODS

Between January 1996 and October 2012, 37 patients with tumours invading the IVC were operated on at the Marie Lannelongue Surgical Center, Le Plessis Robinson, France. Detailed medical history was reviewed, including former malignant diseases, diabetes, smoking status, hypercholesterolaemia, hypertension, coronary heart disease, cardiac function, cerebrovascular insufficiency, chronic obstructive pulmonary disease and liver or kidney diseases. The preoperative work-up included pulmonary function testing with arterial blood gas analysis, spirometry and quantitative lung perfusions. Cardiac risk was assessed by transthoracic echocardiography and coronary angiography in patients with a history of cardiovascular disease. Imaging studies to evaluate the local extension of the tumour included thoracoabdominal computed tomography of the chest and abdomen, selective renal and vena caval angiography and magnetic resonance angiography. Proximal intravascular tumour extent was classified according to guidelines developed by Neves and Zincke [16]: Level I, tumour involving the IVC at the level of the renal vein; Level II, tumour involving the infrahepatic IVC; Level III, tumour involving the retrohepatic IVC and Level IV, tumour involving the supra-diaphragmatic IVC or RA. We added a Level V for tumour thrombus located in the PA. Of note is that involvement of the vena cava was recognized before surgery in all patients.

Surgical preparation

Preoperative selective renal artery ethanol embolization was not undertaken before the operation, not even for RCC [14]. Operations were performed through a median laparotomy, which was extended to a median sternotomy for Level III (retrohepatic IVC), Level IV (supradiaphragmatic IVC or RA) and Level V (PA) tumours (Fig. 1).

Surgical exposure

Level I and Level II tumours. Exposure of the inferior vena and renal veins was obtained through a midline laparotomy and an extensive Kocher manoeuvre. Before clamping, patients received 50 IU/kg of unfractionated heparin. After cross-clamping the IVC below and above the tumour level, resection was performed either by cavotomy and tumour thrombectomy or by en bloc resection of the IVC.

Level III and IV tumours. When the tumour invaded the retrohepatic or suprahepatic IVC, surgical exposure was obtained through a median sternotomy and a supraumbilical laparotomy. Full liver mobilization was required to provide access to the infrahepatic portion of the IVC. This was performed by dividing the left triangular ligament and the falciform ligament, and the incision was carried around each portion of the divided falciform ligament to the right superior coronary ligament. The central diaphragmatic tendon is dissected in the midline until the supra-diaphragmatic intrapericardial IVC and the hepatic veins are identified. The lesser omentum on the left side of the hepatic hilum is also incised. The liver is rolled to the patient’s right, exposing the junction between hepatic veins, upper IVC and RA. For full exposure of the RA, the pericardium is opened and the intracardiac IVC is controlled. The liver rotation to the right fully exposes the retrohepatic IVC from the renal veins to the RA, and facilitates the venotomy from the RA to the infrahepatic IVC. The only other remaining structure in front of the IVC is the porta hepatis, which is controlled with a Rummel tourniquet or a vascular clamp to allow Pringle’s manoeuvre (occlusion of blood inflow to the liver).

Having achieved this exposure, tumour resection is undertaken (nephrectomy, adrenalectomy, hepatectomy etc). This also enhances the exposure to the IVC at the level of the renal veins and retrohepatic segment. Local and regional lymphadenectomy is performed when preoperative or intraoperative findings suggest lymph node involvement. Thereafter, the IVC is exposed for tumour thrombectomy. Haemostasis is obtained before initiating CPB.

Level V tumours. Pulmonary artery embolic tumour removal is performed through the standard thrombendarterectomy approach that we have reported in the past [17]. Pulmonary artery embolic tumour removal concomitant with nephrectomy should be considered as an extension of the vena caval tumour as opposed to a distant metastasis, and is performed on CPB with DHCA [7].
Surgical strategy

**Cardiopulmonary bypass.** The ascending aorta is cannulated in the standard fashion. Venous drainage is ensured by the insertion of a cannula into the superior vena cava (SVC) and another into the IVC below the tumour thrombus in a retrograde direction (usually below the renal veins). CPB is established.

If CPB alone was used, we did not cross clamp and arrest the heart. Then, we managed the bleeding by controlling the hepatic artery and porta and snaring the IVC around the inferior canula. It is also important not to use a pump sucker to prevent tumour seeding to reservoir and systemic circulation.

The tumour can be excised en bloc by making an incision from the RA to the anterior wall of the IVC under direct vision. After closure of the RA and repair of the vena cava, the circulation in the rest of the body is resumed, and warming is continued until the body temperature reaches 37°C.

Patients are weaned from CPB and anticoagulation is reversed by protamine administration in the standard fashion.

**Deep hypothermic circulatory arrest.** If a PA tumour thrombus is present, the patient’s temperature is cooled down to 18°C in order to perform DHCA. The ascending aorta is cross-clamped and both the IVC and SVC cannulas are snared. Pringle’s manoeuvre is also performed for back bleeding control.

Tumour removal and vascular reconstruction technique

Segmental caval resection was performed in patients who had a primary malignancy of the vena cava or massive tumour invasion of the wall of the IVC. Reconstruction was performed only if the vena cava was patent before the operation. We use a ringed polytetrafluoroethylene graft for reconstruction purposes (W.L. Gore & Associates, Inc., Flagstaff, AZ, USA). In these patients, the vena cava was clamped with straight vascular clamps, and anastomoses were performed with monofilament sutures. When a thrombectomy or a partial excision of the vessel wall was performed, the IVC was closed with direct suturing.

Postoperative care

Patients treated with a caval wedge resection and reconstruction by direct sutures received prophylactic low-dose heparin until hospital discharge. Patients with full caval reconstruction using the Gore-tex graft initially received unfractionated heparin at a therapeutic level (partial thromboplastin time of 50–60 s) and were then switched to oral anticoagulation for 6 months.

Perioperative complications were registered in the database and included renal failure requiring dialysis, respiratory failure (pneumonia or ARDS) requiring ventilatory support and major postoperative bleeding requiring reintervention.

Statistical analysis

Analysis of categorical variables was performed using the $\chi^2$ test. Survival curves for each prognostic variable on overall survival were estimated according to the Kaplan–Meier method. The terminal event was death attributable to all causes. The statistical significance of the differences in survival distributions among the prognostic groups was evaluated by the log-rank test. Statistical difference was reached with a $P$-value of <0.05. Data were analysed using SigmaPlot for MAC OS, version 9.0 (Systat Software, Inc., San Jose, CA, USA).

**RESULTS**

Between January 1996 and December 2012, 37 patients underwent surgical treatment of malignant tumours invading the IVC. This included en bloc resections of a circumferential caval segment, partial caval wall excision, IVC or PA thrombectomy. There were 25 men and 12 women with a median age of 50.4 years (range 14–75 years). Patients and tumour characteristics are listed in Table 1. Neoadjuvant therapy included chemotherapy in 12 patients, radiation in 2 and chemoradiation in another 2. Fifteen patients (40.5%) had one previous procedure at surgical resection. Previous procedures were hepatectomy in 1 case, nephrectomy in 3, orchidectomy in 6, hysterectomy in 1 and attempted resection in 4.

No patient had prior cardiac surgery. The mean time between the two surgeries was 23 ± 20 months.

Tumour infiltration was located at the hepatic and suprahepatic level in 23 patients (62%), the renal vein level in 16 (16%), and the infrarenal segment in 8. Fourteen patients (38%) had right heart involvement, of whom 5 had a tumour thrombus located in the PA (16%) (Table 2).

Operative details are listed in Table 3. Pringle’s manoeuvre was needed in 12 patients (35%) with a mean clamping time of 26 ± 14 min. CPB was performed in 15 patients (41%) with a mean duration of 69 ± 57 min; DHCA was used in 5 patients (14%) with a mean time of 26 ± 7 min. In 1 case of Level III tumour extension, CPB was used because the tumour was very mobile and extended just to the level of the hepatic vein. The tumour was removed by cavotomy with thrombectomy and the IVC closed directly in 14 patients (38%). Lateral resection and plasty were performed in 9 cases (24%) whereas circumferential resection with graft reconstruction was necessary in 14 (38%). Replacement for retrohepatic extension was performed in 5 cases using PTFE graft. A direct anastomosis was instituted between the hepatic veins and the RA in one case and the PTFE graft in 1.

Postoperative complications occurred in 25 patients (68%) (Table 4). Three patients needed to be taken back emergently to

<table>
<thead>
<tr>
<th>Table 1:</th>
<th>Patients and tumour characteristics</th>
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<tr>
<td>Number of patients (%)</td>
<td></td>
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<tr>
<td>Men</td>
<td>25 (68%)</td>
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<tr>
<td>Cardiac insufficiency (%)</td>
<td>7 (19%)</td>
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<tr>
<td>Respiratory disorder (%)</td>
<td>6 (16%)</td>
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<tr>
<td>Renal insufficiency (%)</td>
<td>11 (30%)</td>
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<tr>
<td>Reoperation (%)</td>
<td>15 (40%)</td>
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<tr>
<td>Renal cell carcinoma (%)</td>
<td>11 (30%)</td>
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<tr>
<td>Adrenocortical carcinoma (%)</td>
<td>8 (22%)</td>
</tr>
<tr>
<td>Testicular carcinoma (%)</td>
<td>5 (13%)</td>
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<tr>
<td>Uterine leiomyoma (%)</td>
<td>3 (8%)</td>
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<tr>
<td>IVC leiomyosarcoma (%)</td>
<td>2 (5%)</td>
</tr>
<tr>
<td>Retroperitoneal sarcoma (%)</td>
<td>6 (16%)</td>
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<tr>
<td>Hepatic carcinoma (%)</td>
<td>2 (6%)</td>
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the operative room for major bleeding. Two patients died during the postoperative period (5.4%). Both patients had extensive IVC involvement with thrombus extending to the right heart, and both had preoperative renal insufficiency which became worse and required dialysis after surgery. Multiorgan failure occurred after pulmonary infection in 1 case and urinary infection in the other. The mean intensive care unit length of stay was 7.3 ± 7.7 days.

Complete tumour resection (R0) was achieved in 23 patients (62%), whereas 6 (16%) had positive macroscopic margins (R2) and 8 (22%), positive microscopic margins (R1 resection). The mean follow-up period was 38 ± 45 months. Primary patency of the reconstructed IVC was 90% at 1 year by CT scan. The median survival was 18 months. The estimated 1-, 5- and 10-year overall survival rates were 68.1, 45.7 and 40%, respectively (Fig. 2). The tumour level in the IVC, parietal invasion of IVC and the distant metastatic status were not found to impact survival. However, complete (R0) resection was associated with a better survival (P = 0.03) (Fig 3).

DISCUSSION

Our series includes patients with various types of malignant tumours invading different levels of the IVC. The diverse aetiology of cancers and the relatively small number of patients preclude firm conclusions regarding the impact of these operations on survival, even though there seems to be a trend towards overall survival improvement with an aggressive surgical resection [8]. Furthermore, the long recruitment time could impact our results. Indeed, improvements that have been made in CPB and particularly in DHCA during pulmonary endarterectomy for chronic thromboembolic pulmonary hypertension prompt us to use this technique preferentially.

Patients selection

Replacement and reconstruction of the resected IVC is relatively controversial, as patients with extensive intraluminal involvement can undergo an open thrombectomy alone or a patch
reconstruction, without a significantly higher risk of late recurrence from the venous wall [17]. If radical tumour resection and caval replacement are to have any role, the operative mortality and morbidity must therefore be low. This requires careful patient selection, and long-term durability of the grafts. Preoperative radiological evaluation is critical in that setting: CT scan imaging should define the extent of the tumour and the presence of metastatic disease.

Approach

Use of a laparotomy/sternotomy approach is mandatory if the tumour extends to the retrohepatic or suprahepatic part of the IVC. We prefer this approach to a Chevron or thoracoabdominal incision requiring a more extensive diaphragmatic division [15, 18]. A midline incision extended to the diaphragmatic centre in fact provides an excellent exposure of the suprahepatic IVC. Division of the ligament attachments of the liver, ligation of the diaphragmatic veins and rotation of the liver to the right side are required to achieve this exposure. The latter is, however, suboptimal in the presence of an accessory left hepatic artery, requiring its ligation. Furthermore, combining sternotomy with a supraumbilical laparotomy provides good conditions for establishing central CPB, and the treatment of intracardiac or intrapulmonary extension if necessary. When using CPB only, it is necessary to clamp the hepatic artery and the porta hepatitis, but this is limited to the period during which the liver and the kidneys undergo warm ischaemia, thus increasing the surgical risk.

Surgical strategies

If the upper end of the tumour does not extend beyond the lower edge of the liver (Levels I and II), a strictly abdominal approach by laparotomy can be used without CPB [1].

Level III, IV and V tumours pose special challenges for operative treatment. Different strategies are possible for those difficult cases.

Resection without CPB

Several operative strategies avoiding CPB have been reported in the literature. These include staple ligation of the IVC as a palliative solution for unresectable retrohepatic vena caval tumour invasion [19].

Cerwinka et al. [20] described their experience using a liver transplant technique with resection of IVC tumour thrombi without CPB avoiding sternotomy. Twelve patients underwent radical nephrectomy with complete extraction of the tumour thrombus from the supradiaphragmatic IVC without CPB or DHCA. The postoperative mortality rate was 16%. Four patients (33%) sustained the Budd–Chiari syndrome, and 3 (25%) presented with postoperative tumour recurrence. The authors mentioned in their discussion that the non-CPB approach is plagued by problems of profound intraoperative hypotension, suboptimal thrombectomy, risk of tumour embolization in the RA and pulmonary tree, and the risk of unpredictable bleeding associated with warm ischaemic injury to the liver and kidneys [20]. In fact, clamping of the IVC without CPB will invariably cause an abrupt reduction of the venous return, leading to severe hypotension, bleeding from the uncontrolled suprahepatic veins and venous hepatic congestion.

Skinner et al. [6] developed a technique for the safe removal of extensive vena caval thrombi extending up to the RA without the need for CPB or hypothermic arrest. They reported short warm liver and kidney ischaemia times with postoperative complications in 60% of the patients (transient hyperbilirubinaemia, renal dysfunction and respiratory failure). However, there were significant intraoperative complications with 3 deaths (2 of which were due to exsanguination and 1 to a massive pulmonary tumour embolization). There were 4 other perioperative deaths caused by sepsis and multiorgan system failure, resulting in an operative mortality rate of 13%.

Resection with venovenous shunt

For the Level III extension, a laparotomy approach with venovenous shunt/perfusion from IVC to SVC through peripheral cannulation can be an alternative to omit median sternotomy, while abrupt reduction of the venous return that may cause severe hypotension can be avoided.

Resection with CPB without DHCA

Minimal-access approaches with right subclavian artery cannulation and cartilage rib resection for CPB have been described [21]. Peripheral cannulation and antegrade selective cerebral and cardiac perfusion associated with systemic circulatory arrest to protect the brain and the abdominal viscera are alternative approaches that could not be easily standardized [18, 22].

Authors have treated Level III and IV extensions using CPB without DHCA, which allows for a shorter bypass time. However, this strategy has several disadvantages, including reduced visualization and exposure due to blood in the field, hepatic congestion, higher risk of embolization; higher risk of warm hepatic and renal ischaemia, hypoxic liver impairment and acute tubular necrosis [13]. In the report by Stewart et al. [13], all of the 20 patients received blood product transfusions (average of 10 units of blood, 6 units of platelets and 2 units of fresh frozen plasma). Serious perioperative morbidity occurred in 3 patients, transient dementia in 2, and 1 required mediastinal re-exploration for postoperative bleeding. In addition, 3 patients had transient elevation of serum transaminase and bilirubin levels postoperatively. In another report by Tsuji et al. [23], 2 patients died during the early postoperative period because of retrohepatic caval injury and intraoperative pulmonary embolism.

Resection with CPB with DHCA

Similar to our experience here, Navia et al. [15] reported that CPB with DHCA has several advantages: a bloodless surgical field with reduced risk of cellular or tumour spreading, pulmonary embolization, and fatal haemorrhage. There is also a reduced risk of warm renal and hepatic ischaemia, reduced risk of incomplete tumour excision, and optimal visualization of the IVC lumen and of the RA, without the need for extended retroperitoneal dissection. Reported disadvantages of DHCA are extended bypass time as a result of rewarming, postoperative bleeding and coagulopathy. As we describe in our report, Budd–Chiari syndrome, venous hepatic congestion, severe hypotension and catastrophic bleeding can all be avoided using CPB. Also, in our experience, strategies...
without CPB or DHCA should not be considered for patients with cavoatrial extension (Levels IV and V) due to the risk of tumoural embolization. Indeed, the tumoural thrombus is very mobile in the heart. Furthermore, blind clamping on the terminal part of IVC or the RA may cause coronary sinus occlusion and cardiac arrest.

In our series, 14 patients had right heart involvement (35%) requiring CPB, in whom 5 (14%) had a tumour thrombus located in the PA requiring CPB with DHCA. This tumoural thrombus is usually difficult to cleave from the parietal wall. Another advantage of DHCA is the presence of the bloodless field needed to find a correct cleavage plane for a R0 resection. Indeed in 1 case with a Level V extension, 2 years after the first resection a right lower lobectomy was performed for a recurrence that was perhaps an incomplete resection.

**Unique or staged procedure**

In the case of renal cell carcinoma, PA tumour embolism is rare, and most cases in the literature represent an intraoperative tumour embolism during mobilization and removal of the primary tumour [24]. Although a staged procedure with either nephrectomy or pulmonary tumour embolectomy performed first has been reported [25], we prefer a concomitant removal of pulmonary tumour embolus and primary renal tumour in a single setting, as other authors do as well [7]. The operative mortality in our series is relatively low, given the magnitude of the procedure, and is consistent with the literature [17]. We also report an estimated mean survival of 18 months, taking into account a 41% re-resection rate. Major complications included three reoperations for major bleeding and one terminal renal insufficiency; there were no significant neurological events.

**CONCLUSION**

In conclusion, we believe that a multidisciplinary approach and careful evaluation of patients with IVC tumour invasion are mandatory for appropriate patient selection. Full mobilization and rightward rotation of the liver through an extended midline incision is a safe approach for tumours involving the retrohepatic IVC, the RA and/or PA, CPB, with or without DHCA is a safe and efficient adjunct to the procedure. This one-stage approach allows the concomitant removal of the primary tumour and any cavoatrial tumour embolus and/or PA embolus. Radical resection of the IVC is also feasible in carefully selected patients. A preoperative standardized surgical strategy is required to obtain an adequate resection with low morbidity and mortality rates, and to achieve acceptable survival rates. Complete resection of the tumour (R0) is of paramount importance in that regard.

**Conflict of interest:** none declared.

**REFERENCES**


**APPENDIX. CONFERENCE DISCUSSION**

Dr L. Spaggiari (Milan, Italy): Once again the Dartevelle group has shown the scientific community another important challenging surgical experience, moving further and further any technical limits to curing cancer. The authors report an experience of 37 patients over 16 years affected by tumours invading the inferior vena cava to different levels who underwent different surgical procedures...
approaches. This is obviously a technical paper, but despite the technical excellence, the paper presents some oncological and methodological bias.

First, a limited number of patients were studied over a long period of time, 37 patients in 16 years corresponds to 2.3 patients per year. For this reason, this technique can hardly be extrapolated to be able to have a good learning curve. Second, there were too many different tumours involved in the study to permit oncological results to be deduced. Even though the surgical technique was performed by very experienced surgeons, 37% of the inferior vena cava resections were incomplete.

You state in the paper that the technique will produce a long-term survival, but your median survival was 18 months. Besides, it is difficult to compare different surgical techniques due to the different levels of inferior vena cava infiltration. Level I and level II are standard abdominal surgery, level III and level IV start to be challenging surgery, and level V is almost prohibitory.

Finally, you did not mention in the paper any details regarding adjuvant chemotherapy, which I think is very important in this setting. You mentioned that there is no difference between patients with and without systemic metastasis, so I think that the prognosis is correlated to the medical treatment and not to the surgery. It is important to focus on that because 37% of your patients had an incomplete resection.

My first question is, what was the mortality at two and three months after operation? Second, in spite of the limited number of patients, do you think there is one type of cancer rather than another that could really benefit from this type of surgery?

Dr Fabre: In answer to your first question, the in-hospital mortality was 5.4%, the two-month mortality 8%, and the three-month mortality 11%. The two patients who died during the hospital stay had extensive IVC involvement with thrombus in the right heart; both had preoperative renal insufficiency which got worse after the surgery, with the need for dialysis. Multi-organ failure occurred after pulmonary infection in one case and urinary infection in one case.

Your second question regarding the type of cancer that can really benefit from this surgery is very difficult to answer. Also, there is a trend toward improvement in survival in these patients. An aggressive management could produce long-term survival. The diverse oncology of cancer and the small number of patients preclude a conclusion regarding the impact of this operation on survival. Also, I think the question before operating on these patients is ‘can I do an R0 resection?’ I think there is no place for chemotherapy for those patients; surgery is a life-saving procedure.

Dr Spaggiari: Do you have any experience in your team with the non-surgical treatment of such a patient?

Dr Fabre: Usually patients are referred to our surgical centre for surgery. We discussed some cases at the Gustave Roussy Institute. We have a discussion for all patients, but usually those who are referred come for surgical treatment.

Dr P. Van Schil (Antwerp, Belgium): These are technically-demanding procedures. Regarding the use of cardiopulmonary bypass, there is always a concern about immune suppression of the patients after the operation. Did you look at local or distant recurrences in those patients you had to put on cardiopulmonary bypass, and especially those patients having circulatory arrest, compared to the other group of patients?

Dr Fabre: I did not carry out any statistical analysis for recurrence related to cardiopulmonary bypass, but I think it is a very interesting question.