Superior vena cava resection with prosthetic replacement for non-small cell lung cancer: long-term results of a multicentric study

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Abstract

Objectives: Superior vena cava (SVC) resection with prosthetic replacement for non-small cell lung cancer (NSCLC) is infrequently performed and oncological results are unclear. To establish a historical benchmark for this extended surgery, we have updated and reviewed data from four international centers.

Methods: Data were obtained through retrospective chart review. Prognostic factors were analyzed using first univariate techniques and subsequently multiple regression (logistic regression). Kaplan–Meier overall survival was calculated and prognostic factors examined by log–rank test and the estimation of hazard ratios using Cox regression.

Results: From 1985 to 2000, 28 patients underwent SVC resection with prosthetic replacement for NSCLC. During the same period, 65 patients underwent partial SVC resection. Induction treatment was performed in 25% of patients. The resection was done for T involvement in 22 patients (79%), and for N2 involvement in the remaining. There were 12 tracheal sleeve resections, four pneumonectomies, and 12 lobar or sublobar resections with or without bronchoplasty. The median clamping time was 40 min. The median diameter of the prosthesis used was No. 14. Pathological examination showed direct SVC invasion (T4) in 79% of patients, whereas N2 disease was present in 50% of patients. Median intensive care unit and hospital stay were 3 and 20 days, respectively. The postoperative morbidity and mortality were 39 and 14%, respectively. The overall 5-year probability of survival was 15% (median of 9 months, range 0–105 months). Patients who underwent partial SVC resection during the same period had a significantly higher probability of survival (P = 0.03). Induction chemotherapy was associated with a significant increase of postoperative morbidity in multivariate analysis. None of the potential prognostic factors analyzed in multivariate analysis were associated with survival, but the type of resection (sleeve pneumonectomy/pneumonectomy) were borderline significant.

Conclusions: SVC resection with prosthetic replacement should not be considered an absolute contraindication in patients with NSCLC; however, the poor oncological results suggest more restrictive and severe criteria of patient selection (mediastinoscopy, induction treatment, no pneumonectomy, no N2 disease). © 2002 Elsevier Science B.V. All rights reserved.

Keywords: Extended resection; Superior vena cava resection; Prosthesis replacement; Lung cancer; Advanced lung cancer; Stage IIIB; Polytetrafluoroethylene

1. Introduction

Even though complete surgical resection is the only reliable treatment to cure non-small cell lung cancer (NSCLC), the involvement of the superior vena cava (SVC) system is still globally considered to be a contraindication to surgical resection [1]. To date, only a few centers have explored the possibility of resecting SVC system for NSCLC, but oncological results are uncertain and are influenced by the low number of cases [2–8] (Table 1). The degree of SVC infiltration is one of the most important topics of debate; limited SVC infiltration can be easily ‘en bloc’ removed by a tangential resection without any vessel clamping and reconstruction and without adding morbidity to lung resection; by contrast, more advanced involvement requires full SVC resection and graft replacement. This last condition is a more important procedure either for technical or oncological problem or for both. The results of prosthetic SVC replacement for NSCLC in terms of postoperative morbidity–mortality and long-term outcome remain unexplored due to the very low number of patients reported in the literature.
Table 1
Literature review concerning superior vena cava system resection: consecutive series with more than three patients from 1989 to 2000 with data concerning survival available in the text

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Patients</th>
<th>PTFE graft replacement</th>
<th>Postoperative mortality no. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nakahara</td>
<td>1989</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Piccione</td>
<td>1990</td>
<td>6</td>
<td>0</td>
<td>1 (17%)</td>
</tr>
<tr>
<td>Dartevelle</td>
<td>1991</td>
<td>6</td>
<td>6</td>
<td>1 (17%)</td>
</tr>
<tr>
<td>Thomas</td>
<td>1994</td>
<td>15</td>
<td>4</td>
<td>1 (7%)</td>
</tr>
<tr>
<td>Tsuchiya</td>
<td>1994</td>
<td>32</td>
<td>7</td>
<td>7 (22%)</td>
</tr>
<tr>
<td>Spaggiari&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2000</td>
<td>25</td>
<td>7</td>
<td>3 (12%)</td>
</tr>
<tr>
<td>Spaggiari&lt;sup&gt;b&lt;/sup&gt;</td>
<td>2000</td>
<td>6</td>
<td>3</td>
<td>0</td>
</tr>
</tbody>
</table>

<sup>a</sup> Marie Lannelongue Hospital (Paris, France) experience.

<sup>b</sup> European Institute of Oncology experience of a series of double extended (tracheal sleeve and SVC) resection.

The purpose of this study is to establish a historical benchmark for this extended surgery (prosthesis replacement) by updating and reviewing survival, morbidity, and mortality data from four international centers.

2. Materials and methods

From 1963 to 2000, 109 patients with advanced NSCLC underwent pulmonary resection associated with SVC resection in four international Thoracic Surgical Departments. Starting from 1985, 28 of those patients underwent complete SVC system resection with prosthetic replacement and they constitute the subject of this analysis (Table 2); during the same period (1985–2000), 65 patients underwent partial SVC resection without graft replacement.

Data Collection form was developed and used to abstract demographic clinical and follow-up data in all patients who underwent a lung resection for NSCLC treatment in the participating hospital between 1963 and 2000. The abstraction form included section on pre-surgery, oncological staging, surgery, procedures with detailed registration of the resection, complications, and follow-up.

2.1. Statistical methods

The primary end points of the study were postoperative deaths from any cause following SVC resection and prosthesis replacement, the occurrence of major complications, and survival.

2.2. Univariate analysis

Chi-square test and Fisher’s exact test were used to compare the distribution of categorical prognostic factors across morbidity and mortality status. Continuous data (i.e., age) were expressed using medians. \( P \)-values were derived from two-sided tests. A difference was considered statistically significant if the associated \( P \)-value was 0.05. The following prognostic variables were evaluated: induction treatment (any vs. none), resection type (pneumonectomy and sleeve pneumonectomy vs. other), indication for resection (SVC invasion by T or by N), and type of prosthesis (simple or ringed).

2.3. Multivariate analysis

Logistic regression models using Proc Logistic in SAS (Cary, NC, USA) were fit to death in the postoperative period (yes/no) and occurrence of major complications (yes/no). The models allowed the adjustment for potential confounders. The Wald chi-square test were used to assess the importance of each variable in the logistic model.

2.4. Survival analysis

Cumulative survival curves were obtained with the Kaplan–Meier method. Differences between the curves, when comparing selected prognostic factors, were tested for significance using the log–rank statistics. Cox proportional-hazard regression models were used to estimate the hazard ratios and 95% confidence interval adjusting by age and center. Survival was assessed for sub-groups defined by

Table 2
Superior vena cava resection with prosthesis replacement for NSCLC: International Data Set (range year of surgery according to the different centers)

<table>
<thead>
<tr>
<th>Center</th>
<th>Number of patients</th>
<th>Year of surgery (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) European institute of oncology, Milan, Italy</td>
<td>7</td>
<td>1998–2000</td>
</tr>
<tr>
<td>(B) Hotel-dieu hospital, Paris, France</td>
<td>6</td>
<td>1988–1995&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>(C) National cancer center, Tokyo, Japan</td>
<td>10</td>
<td>1985–1996</td>
</tr>
<tr>
<td>(D) Ste Marguerite University Hospital, Marseille, France</td>
<td>5</td>
<td>1991–1998</td>
</tr>
</tbody>
</table>

<sup>a</sup> This series represent the experience of Professor J.F. Regnard, Dr P. Magdeleinat, during their period at the Marie Lannelongue Hospital, Paris, France.
the following variables: induction treatment (any vs. none), resection type (pneumonectomy and sleeve pneumonectomy vs. other), pT (T1, T2, T3 vs. T4), pN (N0/N1 vs. N2), and indication for resection (SVC invasion by T vs. SVC invasion by N). Cumulative survival and proportional-hazard ratios were calculated after censoring observations beyond 60 months following surgery.

3. Results

A total of 28 patients (24 males) with a preoperative histological diagnosis of NSCLC, received a prosthetic SVC replacement. The median age in this group was 60 years with patients ranging between 38 and 77 years of age. Eight patients (28%) underwent mediastinal investigation by cervical mediastinoscopy (seven patients) and left anterior mediastinoscopy (one patient); seven patients (25%) received preoperative treatment (four cisplatin-based chemotherapy, two cisplatin-based chemotherapy and radiotherapy, and one radiotherapy).

Surgical approach was posterolateral thoracotomy in ten patients, lateral thoracotomy in seven, hemiclavemshel in one, and sternotomy in six patients. Four patients underwent both sternotomy and posterolateral thoracotomy. An associated cervical or a cervico-thoracic approach was used in 21% of cases (three cervicotomy, one transclavicular, and two transmanubrial approaches).

Sixteen patients (57%) underwent pneumonectomy (12 of those patients underwent tracheal sleeve pneumonectomy, 43%). The other patients underwent lobectomy (n = 5), segmentectomy/wedge (n = 3), sleeve lobectomy/bilobectomy (n = 3), tracheal sleeve lobectomy (n = 1).

3.1. Superior vena cava operative procedures

The indication for SVC resection was the direct involvement of the vessels by the tumor (T4) in 22 cases (79%), and by extracapsular mediastinal lymph nodes (N2) in six cases (21%). Data regarding the timing of SVC resection with respect to lung resection was available for 24 patients. The vessels were resected before lung resection in 62% of cases. Data regarding anticoagulation therapy before SVC resection was available for 15 patients who received intravenous sodium heparin (0.5 mg/kg) before clamping.

SVC replacement was accomplished by polytetrafluoroethylene (PTFE) graft in all cases. A single lumen prosthesis was used in 26 patients (93%), whereas in two patients, SVC system was revascularized by two independent single lumen grafts. Ringed type prosthesis was used in 19 cases (68%). The median size of the prosthesis was No. 14 (range No. 8–22). Clamping time was available for 15 patients, with a median time of 40 min (range 15–105 min).

There were 14 (50%) replacements of the SVC trunk, sparing the confluence of both innominate veins. Proximal anastomosis was performed in the right atrium in six cases and in the SVC in the remaining eight cases. Nine patients (32%) underwent truncular SVC system resection followed by revascularization with anastomosis in the left innominate vein. Proximal anastomosis was performed in the right atrium in four patients whereas in the other five patients it was done in the SVC. Three patients underwent complete resection of right (n = 1) and left (n = 2) innominate veins with subsequent prosthetic replacement of the innominate vein resected, associate with tangential resection of the SVC. Finally, two patients underwent double prosthesis replacement of the SVC system; the first prosthesis revascularized right SVC system with a SVC-right innominate vein anastomosis, whereas the second one revascularized the left SVC system with a right atrium-left innominate vein anastomosis.

3.2. Postoperative pathologic features

There were 19 squamous cell carcinoma (68%), eight adenocarcinoma (29%), and one undifferentiated large cell carcinoma.

Twenty-two patients (79%) had the direct involvement of the SVC system by the tumor (T4); four patients had a T3 disease, whereas the remaining two patients showed a T1 disease.

The lymph node status was N0 in eight patients (29%), N1 in six patients (21%), and finally N2 in 14 patients (50%). Resection was complete in 21 (75%) patients. In five (18%) and two (7%) patients, respectively, a microscopic and macroscopical residual tumor was found on specimen analysis.

3.3. Postoperative course

No periperal complications due to the SVC clamping were observed. Major postoperative morbidity and mortality were 39% (n = 11) and 14% (n = 4), respectively. There was one postoperative bleeding requiring re-thoracotomy, one pulmonary embolism followed by postoperative death, two postpneumonectomy edema fatal in one case, one lung abscess, one bronchial fistula with postoperative death, three early prosthesis thrombosis, one acute renal failure, one sudden death without organic causes.

Thus, the majority of complications were pulmonary. There were also three (11%) SVC-related complications (early thrombosis) that were medically treated; prosthesis infection developed after two (7%) pulmonary complications (lung abscess and bronchial fistula). In one case (after lung abscess) this catastrophic complication was cured by completion of pneumonectomy and intra-thoracic latissimus dorsi muscle myoplasty. The patient was alive 4 years after operation without evidence of disease and with patency of the graft.

Data concerning anticoagulant regimen during postoperative period and after hospital discharge are incomplete. However, the majority of patients underwent heparin or low-weight heparin therapy during postoperative period followed by coumadin at discharge.
The median intensive care unit and hospital stay were, respectively, 3 days (range 0–42 days) and 20 days (range 7–160 days).

3.4. Long-term results

Adjuvant chemotherapy and radiotherapy were given, respectively, in two (7%) and eight (29%) patients, respectively. Follow-up of prosthesis status were available for 16 patients. Computed-tomography (CT) thoracic scan was used in the majority of these patients (62%) to investigate graft patency. Seven patients (44%) developed graft thrombosis (including three postoperative early thrombosis) during a period ranging from 5 to 390 days postoperatively. Thus, the rate of late thrombosis was 30%.

Survival data were available on 27 patients. At the completion of the study five patients (18%) were alive. The overall median survival was 9 months (confidence interval 95%: 4.7–16.7 months; range 0–105 months) The overall estimate 1-, 2-, and 5-year (Kaplan–Meier) survival rates were 36, 20, and 15%, respectively (Fig. 1). The median survival of the 65 patients operated on during the same period was 16.7 months; range 0 to 160 days). The 5-year probability of survival were 15 and 32%, respectively, in two (7%) and eight (29%) patients, respectively, 3 days (range 0–42 days) and 20 days (range 7–160 days).

3.5. Comparison by prognostic factors

Induction treatment was found the only variable associated with the risk of developing a major complication. Seventy-one percent of patients who underwent induction treatment developed a major complication, with respect to 26% of patients who did not undergo induction treatment ($P = 0.04$). This significant association persisted after adjusting in multivariate analysis for age, resection type, pN, indication for resection and type of prosthesis ($P = 0.045$).

Concerning postoperative mortality no statistically significant prognostic factors were identified.

However, all postoperative deaths occurred in patients who underwent a pneumonectomy/sleeve pneumonectomy (four out of 15, 27%). No postoperative deaths were reported in the remaining patients who underwent less extensive pulmonary resections. The association between postoperative death and resection type was only of borderline significance ($P = 0.08$).

None of the prognostic factors selected as potentially influencing long-term survival was found to be associated with survival. However, the hazard ratio (HR) in patients undergoing an extended pneumonectomy was higher (HR = 3; CI 95%: 0.9–10) ($P = 0.08$) as compared to patients who received other types of resection after taking into account age and center (hospital) differences.

4. Discussion

Extended resection for NSCLC is, to date, a topic of debate. The possibility of attaining good local control with low postoperative morbidity and mortality could be a key in the multimodality treatment of such extended disease.

Regarding SVC involvement by NSCLC, a literature review of the last 10 years (Table 1), showed that less than 100 patients underwent surgical resection of the SVC system and about one-third underwent graft replacement. In these series the overall postoperative mortality ranged from 0 to 22%. However, pooling different types of SVC resections and reconstruction (partial and complete SVC resection; running suture, patch, prosthesis), reveals non-homogeneous postoperative outcome and long-term survival. The involvement of the SVC system influences the type of resection and the subsequent reconstruction. Limited involvement can be safely removed en bloc by means of either tangential resection with a TA vascular stapler or tangential clamping and running suture without complete SVC system clamping. By contrast, a more extensive involvement requires prosthetic replacement. In this second condition, surgical management is difficult and perioperative anesthesiological, and surgical problems are common.

![Fig. 1. Survival curves (Kaplan-Meier method, Log–Rank test) of patients who underwent complete SVC resection with prosthetic replacement (curve B); patients at risk at 12, 24, 36, 48, and 60 months following resection were 9, 4, 3, 3, and 1, respectively. Curve A shows the series of patients who underwent partial SVC resection without graft replacement during the same period. The 5-year probability of survival were 15 and 32%, respectively, and the comparison by log–rank test was significant ($P = 0.03$).](image-url)
Moreover, the oncological value of this extended surgery remains unknown due to the low number of reported cases.

The results deriving from the present series provide data about three aspect of this ‘extreme’ surgery: anesthesiological intraoperative management and surgical technical procedures influencing postoperative morbidity and mortality, and long-term oncological results.

Complete SVC clamping during prosthetic replacement causes very important hemodynamic variations in the head and neck and brain venous system. As a result of SVC clamping, an increase of the brain venous pressure develops, with the associated risk of irreversible brain edema. Patients with NSCLC candidate to SVC resection with prosthetic replacement, usually do not have chronic SVC syndrome, thus the effects of the clamping are immediate and are visible [9]. After few minutes from the clamping a head and neck edema with cyanosis and petechs develop, but these signs are reversible after declamping.

By contrast, there is no agreement regarding the time of brain edema onset and the possibility of the irreversible brain damage. Even though it has been experimentally demonstrated that a 1-h of SVC clamping can be well tolerated in non-human primates [10] and dogs [11], others [9,12] have not clinically confirmed this. Dartevelle et al. [13], demonstrated the hemodynamic outcome during clamping of an unobstructed SVC. The use of different pharmacologic devices can prevent or retard the development of brain edema maintaining a normal brain gradient pressure and normalizing the cardiac output. In this series, neither preoperative nor postoperative brain complications were recorded after a median clamping of 40 min even in patients with prolonged clamping time (more than 100 min).

Thus, at present, the clamping time limit is not fixed, but to avoid any complication a rapid revascularization is mandatory.

Concerning technical considerations, the four international centers participating in this present study, used comparable surgical technique and the details have been reported in previous papers [5–8]. However, some considerations should be made. Posterolateral thoracotomy is the preferred access to resect SVC for NSCLC whereas sternotomy remain the choice for mediastinal tumors. However, lateral muscle sparing thoracotomy and sternotomy were used in several patients. The choice depended mainly on the personal experience of the respective surgeons. Proximal SVC prosthesis anastomosis (near the heart) can be indifferently performed on the SVC or on the right atrium according to the degree of infiltration by the tumor. In short and truncular replacements, distal anastomosis is carried out on the distal part of SVC using large prosthesis; however, when the confluence of the innominate veins is infiltrated by the tumor, the preference is to revascularize only the innominate veins with a ringed single lumen prosthesis (size No. 12), usually the left (seven).

The regimen of the anticoagulation therapy is not standardized. Although the use of heparin during clamping is accepted and it is one of the most important pharmacological devices during clamping, the type of anticoagulation therapy in the postoperative period and at discharge is not uniform. However, the risk of developing early or late thrombosis probably depends on other factors. Firstly, the presence of a venous collateral bed before resection for a constricted SVC stenosis, might cause restricted flow in the prosthesis and facilitate early thrombosis. Secondly, the use of small lumen prostheses (No. <10) might be another cause of thrombosis [8]. Finally, resection and subsequent prosthetic replacement of only one innominate vein produces a high risk of developing early or late thrombosis; learning from this experience we suggest of avoiding any revascularization when the other innominate vein is spared.

Graft infection is another potential complication but always occurs secondary to serious infective pulmonary complications; therefore, we can argue that the prevention of pulmonary complication may avoid prosthesis infection. However, in the occurrence of this catastrophic event, using complex intrathoracic myoplastic procedure [12,14] may cure some patients.

A high number of pneumonectomies (with or without carinal resection), and complex bronchoplastic procedures are the pulmonary resections commonly associated with this extended vascular surgery, on condition that the neoplasms are very locally advanced. Care must be done before performing an extended pneumonectomy in these patients, considering the impact of such extensive surgery on postoperative mortality and survival (borderline significant in this study).

The only significant prognostic factors identified in the postoperative period is the presence of induction treatment. More patients are required to confirm these data, but we conclude that chemotherapy before surgery can influence postoperative results in such an extended resection.

The most important results of this study derived the long-term survival analysis. Despite anesthesiological and surgical improvements in the recent years, and the presence of some long-term survivors in this series, the overall 5-year probability of survival remains very low (15%). No prognostic factors have been identified in this study, likely due to the low number of patients. Data concerning the impact of extended pneumonectomy on postoperative mortality and survival, though not significant, may suggest exclusion from surgery for patients who need double extended resection (SVC and tracheal sleeve pneumonectomy). Data regarding the significant difference in long-term survival between partial SVC resection and complete resection cases with prosthetic replacement are interesting, suggesting that the difference probably depends on the less extensive mediastinal invasion in the first group and thus a more conservative procedure is required.

Even though no prognostic factors have been identified, strict criteria of patients’ selection must be recommended. All patients candidate to this surgery should undergo new chemotherapy regimens. Even though chemotherapy has
been shown to increase postoperative morbidity (but no mortality), induction chemotherapy may exclude from surgery patients with rapidly evolving disease; moreover, reduction of mediastinal invasion might allow the use of more conservative SVC and pulmonary resections.

The indication for SVC resection was the direct involvement of the vessel by the tumor (T4) in the majority of cases (79%). Comparing the results of this group with those resected for bulky N2 disease, not significant differences in the postoperative morbidity/mortality and long-term survival were recorded. However, a recommendation should be made to perform preoperative cervical mediastinoscopy in all patients to categorically exclude patients with positive R2 mediastinal lymph nodes. Positive but not bulky R4 mediastinal lymph nodes at the mediastinoscopy, taking into account their very strict rapport with the tumor involving SVC (T4), should not be an absolute contraindication to surgical resection. By contrast, patients with T1, or T2, or T3 with pathological N2 direct SVC invasion at the mediastinoscopy should not be considered for resection.

Tracheo-bronchoplastic lobectomy should be used in preference to pneumonectomy; in case of pneumonectomy, attention to the fluid balance should be made during the clamping to avoid postpneumonectomy edema (7% in the present series)[8].

In conclusion, as few long-term survivors are observed, SVC resection with prosthetic replacement should not be considered an absolute contraindication in the management of patients with NSCLC; however, the poor oncological results suggest more restrictive and severe criteria of selection.

Acknowledgements

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References


Appendix A. Conference discussion

Mr K. Moghissi (Yorkshire, UK): Three very quick questions. Number one, do you in fact know the duration of patency, average? Second, do you use an anticoagulant? Third, can you comment why you are not using saphenous vein?

Dr Spaggiari: Thank you for these very interesting questions. I begin with the second. We use intraoperative sodium heparin (0.5 mg/kg) during SVC clamping, and after that, we are presently using low-weight heparin in the postoperative period until six months after hospital discharge. However, there is no agreement, in English-language literature concerning the use of anticoagulation therapy in this vascular surgery.

Concerning the saphenous vein issue, I have no experience in this type of surgery. For PTFE grafts, the anastomoses are very easy to perform a long patency has been reported.

Concerning the graft patency in this series, not all patients were followed up for this problem. However, taking into account the three early postoperative thromboses, 40% of patients developed thrombosis of the superior vena cava graft but without clinical implications.

Mr R. Qureshi (Solihull, UK): How many patients presented with SVC obstruction in your series?

Dr Spaggiari: No patient had a superior vena cava syndrome before surgery; in my opinion, if a patient shows a superior vena cava syndrome for non small lung cancer, it is too late to perform radical surgery.

Mr Qureshi: And how many patients underwent a venogram before surgery?

Dr Spaggiari: None. We performed only CT thoracic scan.
about 7 or 8%, and I don’t understand why your five-year survival rate is so low
and why your postoperative complication is so high.

Concerning the postoperative thrombosis, I have never observed a post-
operative thrombosis after superior vena cava replacement for lung cancer. You can observe some thrombosis after replacement for mediastinal tumor
from one postoperative event but not for total superior vena cava replacement.
When you look at the long-term survival of these patients, it is excellent, and I
don’t agree with your conclusion. Superior vena cava replacement associated
with a tracheal sleeve pneumonectomy is an excellent operation and without
neo-adjuvant treatment. You can do that immediately.

Dr Spaggiari: Concerning one of the considerations, of the three patients
who had early thrombosis, two underwent replacement of the left brachi-
cephalic vein in one case and of the right one in the other case. I think that
prosthetic replacement of only one brachiocephalic vein is not a good opera-
tion. When the contralateral brachiocephalic vein is patent, we prefer, at
present, to not revascularize the vessels involved by the neoplasm. The
postoperative and long-term oncological results of the present series are
those reported before. I don’t know why Professor Dartevelle presents
better unpublished results. Probably the four centers that took part in this
study are not so proficient as Professor Dartevelle.