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Interview with Dr Florence

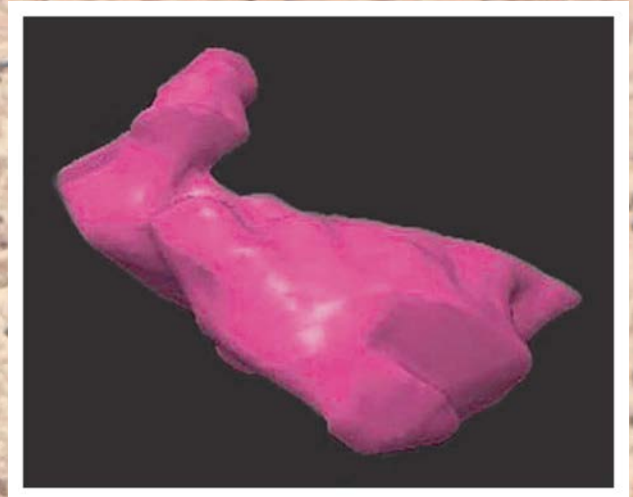
**Laigle-Donadey about the “Surgery
versus Biopsy for Potentially
Operable GBM in the Elderly” trial**

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European Association of

NeuroOncology Magazine 2013; 3 (1)

35-36



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Interview with Dr Florence Laigle-Donadey about the “Surgery versus Biopsy for Potentially Operable GBM in the Elderly” trial

Ufuk Abacioglu

From the Department of Radiation Oncology, Neolife Medical Center, Istanbul, Turkey

Q: Dear Dr Laigle-Donadey, can you tell us about the ongoing “Surgery versus Biopsy for potentially operable GBM in the elderly” trial? I guess this is one of the first randomised trials to assess the role of resection in a specific GBM population. What is the rationale and background for this trial?

A: The incidence of gliomas is increasing in the elderly population. The lack of robust guidelines issued from clinical trials in this population may lead to an inappropriate pattern of care, left to the discretion of the responsible physician. This is particularly true for surgical decisions in this age group, as we know there is a very heterogeneous pattern of neurosurgical care for these patients in France and other countries.

Indeed, it is often believed that elderly patients recover more slowly from surgery and are at a higher risk for post-operative neurologic deterioration. Nevertheless, retrospective studies have found that resection of primary brain tumours could be performed safely in older patients with a positive impact on survival, especially after complete resection.

To date, the value of debulking surgery for GBM in the elderly has been shown in a small Finnish randomised clinical trial reported by Vuorinen et al, in which 23 patients aged > 65 years with malignant glioma (83 % with GBM) were randomly assigned to biopsy only or to surgical resection, followed by radiotherapy. Median survival time was significantly longer with resection (5.6 months) compared to 2.8 months with biopsy. When compared to biopsy, resection was also associated with improved quality of life. These data are encouraging, but they are preliminary because of the very small number of evaluated patients.

A large prospective randomised study evaluating the impact of surgery of malignant gliomas on survival and quality of life in elderly patients is strongly needed and we decided to conduct it.

Q: How is the study designed and what are the inclusion criteria?

A: Inclusion criteria are patient age ≥ 70 , a radiological pattern of probably high-grade glioma and candidacy for surgical treatment with a preoperative KPS > 50 .

Q: What is your definition of the elderly? Why did you choose the age of 70 as a cut-off?

A: We chose 70 years as cut-off for homogeneous purposes because this age is conventionally chosen by French teams regarding elderly patients suffering from malignant gliomas

(confer previously published studies such as RSP [Keime-Guibert F, et al] and TAG [Gállego Pérez-Larraya J, et al]).

Q: Which groups and how many centres participate in the trial?

A: This is a national French trial supported by the Association des Neuro-Oncologues d'Expression Française (ANOCEF) and by Assistance Publique Hôpitaux de Paris (AP-HP). Overall, there are 12 participating institutions in France.

Q: Recent studies focusing on the treatment of GBM in the elderly population have revealed important results and your study will give more information about this disease. Can you critique the rationale of your study, taking into account the results of these studies?

A: Obviously, there is a great dynamism of clinical research in the elderly population, and a lot of emerging publications; I will not comment on recent works in radiotherapy and chemotherapy in this population but I just will focus on surgical studies: Ewert et al recently showed that the extent of microsurgical resection for patients treated with adjuvant radiotherapy and chemotherapy seems to be predictive of a better outcome. This month, Grossmann et al showed that awake-craniotomy is a well-tolerated and safe procedure even in elderly patients and that gross total resection in elderly patients with high-grade gliomas was associated with prolonged survival. However, all these data were based on retrospective analyses and it is crucial to confirm prospectively the role of surgery by means of a study such as ours.

Q: Is there any translational or biological component to this trial?

A: Yes, there is an accompanying translational research package to this trial. We are searching for the usual diagnostic, prognostic, and predictive biomarkers.

Q: How is the accrual proceeding and when do you expect to reach the accrual goal? When can we get the first results?

A: It is a very difficult study to conduct, because it is a huge challenge for patients and their families to participate in a randomised trial with 2 very different procedures (on the one hand a “simple” biopsy and on the other hand debulking surgery). To date, we have accrued 66 of the 135 required patients according to the design of the study. We do not expect first preliminary results within the next 2 years.

Thank you very much!

Further Reading:

Ewelt C, Goepfert M, Rapp M, et al. Glioblastoma multiforme of the elderly: the prognostic effect of resection on survival. *J Neurooncol* 2011; 103: 611–8.

Gállego Pérez-Larraya J, Ducray F, Chinot O, et al. Temozolomide in elderly patients with newly diagnosed glioblastoma and poor performance status: an ANOCEF phase II trial. *J Clin Oncol* 2011; 29: 3050–5.

Grossman R, Nossek E, Sitt R, et al. Outcome of elderly patients undergoing awake-craniotomy for tumor resection. *Ann Surg Oncol* 2012 [Epub ahead of print].

Keime-Guibert F, Chinot O, Taillandier L, et al.; Association of French-Speaking Neuro-Oncologists. Radiotherapy for glioblastoma in the elderly. *N Engl J Med* 2007; 3: 1527–35.

Vuorinen V, Hinkka S, Färkkilä M, et al. Debulking or biopsy of malignant glioma in elderly people – a randomised study. *Acta Neurochir (Wien)* 2003; 145: 5–10.

Dr Florence Laigle-Donadey is the national referent investigator (along with Philippe Cornu, the national neurosurgeon coordinator) of the trial entitled, “Surgery versus Biopsy for Potentially Operable GBM in the Elderly”.

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