

STATUS OF THE HADRONTHERAPY ETOILE-PROJECT IN LYON*

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Abstract

The ETOILE project is the French program for carbon ion beams in cancer treatment. It is now in the final phase. However its development is not only aiming at the building of a medical facility, around the project a broad set of medical and scientific programs have been initiated. The project has been supported by the University of Lyon and extended to the Rhône-Alpes Region and then gained a national visibility with governmental recognition. Many studies have been financed by ETOILE: in beam PET with new solutions, organ motion modelization, tumor cell radioresistance, medico-economical simulation and epidemiological prevision. The facility will be able to produce carbon ion beams and protons. Three treatment rooms are planned two with horizontal beams and one with an isocentric gantry. The facility will be build in Lyon through a process using as much as possible well established technology with the other facilities in Europe. The cost will be around 105 M€ afforded by loans and subventions. The subventions are funded from the Rhône-Alpes Region, the city of Lyon and the ministries of Health and Research. The running cost of the centre, for one thousand patients per year, is estimated to be 21 M€.

INTRODUCTION

The French project of medical centre for carbon ion therapy (CIT) is presently on the way to begin its realisation in the town of Lyon, the third largest town of France. The spike event that initiated the project at Lyon University in 1997 was the *honoris causa* doctorate of Ugo AMALDI, well-known Italian physicist, enthusiastic promoter of charged particle therapy in Europe. Then Pr Jean Pierre GERARD, radiation oncologist of Lyon University, has obtained a quick consensus for a project supported by Lyon University. The rational was based on the experience of NIRS and GSI demonstrating the technical feasibility and the medical interest of a charged particles beam. This type of beam has qualities fundamentally different than photons regarding ballistic and RBE. In 2001 the region of Lyon-Rhône-Alpes, the wealthiest of France, decided to support the project and appointed three full time coordinators: a technical (MB) and a scientific ones (JR_x) and a general manager (JR_t). Since then the project moved on regularly aiming at obtaining the French government authorisation beginning 2004. This authorization has been obtained for the development of ETOILE in Lyon, in May 2005 and presently ETOILE is however at the state of confirmation of the authorization due to the change of the minister. The present management of the project is organized with a

medical direction: Jean-Pierre GERARD, Jacques BALOSSO, Pascal POMMIER ; a scientific direction : Joseph REMILLIEUX ; a technical direction : Marcel BAJARD ; a responsible for European relations : Claude DETRAZ and a project manager : Joël ROCHAT.

DESCRIPTION OF THE PROGRAM

The ETOILE project took his name in early 2002 for the contraction in French of “Site for Oncologic Treatment with Light Ions in European network”, “Etoile” meaning Star in French. ETOILE as a whole has actually four different aspects and could be considered as a quadruple project: i) a scientific project; ii) a medical project; iii) a technological and industrial project and iv) a medical facility for cancer treatment by hadrontherapy. All of these four aspects will continue to live together and develop even when the medical facility will operate.

The Scientific Project

The scientific project, instead of been the added value of the project, has been actually its first condition for existence and acceptance by the French health care system. In fact the French radiotherapy was tremendously behind in the late nineties, therefore, the hadrontherapy project looked too luxurious and the fear of huge financial diversion was rising. Actually radiotherapy needed a moving force in France and we decided to give that aim as the first one for ETOILE. This has been a great success and presently about one hundred researchers are working in close collaboration with the project. The main topics are: the development of highly fast and sensitive detectors for PET imaging, the modelization of organ deformation during breathing cycle, hadrons radiobiology and pharmacomodulation of the response to hadrontherapy of radioresistant cells, the study of carbon ions fragmentation for PET interpretation and hopefully its future use as a dosimetry tool, the fundamental and theoretical study of the RBE modelization starting from the local effect model of GSI group, innovative active beam control. This program has also integrated and participates to support a medical physics school that open in September 2004 in Lyon and Grenoble. The national reorganization of cancer care and cancer research in France has recognized the value of this research program by fully integrating it in the national objectives of cancer research.

The Medical Project

There is no experience of charged particle treatment in France except protontherapy. Therefore, the ETOILE medical project has a rather independent development and, above all, has been so far crucial to obtain the governmental authorization. Its objectives are to define as precisely as possible the indications for CIT, to predict

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the recruitment of the best indications and to demonstrate the feasibility and the medical interest of CIT. It will have to propose a recruitment politic making as clear as possible what will have to be considered as recognized indications and what will have to be studied thought clinical trial. To progress we have many times solicited the NIRS for early results and advices. We are deeply indebted to HIMAC team for its very friendly and helpful support in multiple occasions. From our studies we concluded that 5 to 12% of present radiotherapy indications could be taken in charge by hadrons in the future: 5% for CIT, the rest for protons. This accounts for a rough number of about 7500 cases of CIT indications per year in France. Taking into account the effect of a refine work up, the requirements of clinical trials and the reluctance of some old patients to move far from home, the present figure of ETOILE centre with a capacity of 1000 treatments per year seams consistent as a first offer. It supports also, in case of success, the project of a second French centre for the next decade. The indications have been defined though a multi-step process: i) the thorough screening of any cancers situations by 7 specialized committees selecting about 70 potential indications; ii) the epidemiological study of the incidence of each of these potential indications has been extrapolated from a sample of 1% of the whole annual activity of radiation oncology in France; iii) a scientific survey of the cancer literature to define what could be considered as reference as a treatment and a clinical outcome for the main domains of indications; iv) immediately after the completion of each literature survey, a specific European review committee of experts was gathered for each localisation; the potential indications becoming through this process confirmed indications of CIT. The steps iii) and iv) have been completed so far for H & N tumours, sarcomas, gliomas, and NSCLC. Next ones will be prostate cancer in January 2006 and GIT tumours later on. The step v) just starting, will be to define a common European politic for recruitment, health insurance commitment for care refund of confirmed indications and common definition of early multi-centre clinical trials. This very ambitious project has already involved the participation of about 80 MD. Another part of the medical project is a very detailed economical analysis relying on original medico-economic models to calculate the cost of the centre running according to different criteria and recruitment hypothesis. Through this study, the present figure, with the hypothesis of 1000 treatments per year of 13 sessions each in average, is a cost of 20 960 € (1€ ≈ 1.18 US\$ and ≈ 141 ¥) value of 2014 (at the time of full running of the centre) that is an estimated over-cost of 9 660 € compared to the estimated cost of IMRT at that time. This represents an increase of less than 3% of the present global cost of radiation therapy in France and about 0.2 % of cancer induced hospital expenses in France. Thus it remains a “reasonable” cost fully comparable to other modern anti-cancer treatments not always as much curative as hadrontherapy.

The Industrial Project

The industrial project is another originality of ETOILE. Taking into account that the ETOILE centre will certainly be the third or the fourth in Europe and sixth or the seventh in the World, our choice has been to look for an industrial solution aiming, if possible, at the highest similarity with the other European centres. This choice aims at reducing the cost, hopefully under 100 millions € and at participating to launch an industrial development and therefore an economically affordable dissemination of hadrontherapy. Our present estimation is that one centre for 10 millions inhabitants could be a realistic projection. However, French and European scientific teams able to calculate and to build such machines will be closely associated to the construction to maintain their known how and to provide highly qualified expertise to contracting and contractors. In this project some technological researches are also carried out such as the development of a superconductive gantry.

The Medical Facility

The clinical centre, at last, will be the fruit of the different branches of the project, but as said before, its opening will not ends the other components of the project: the scientific program, the medical one and hopefully the industrial one will step on. The opening of the centre is foreseen for the end of 2010 and the rising activity to full running should take 3 to 4 years. The present figure is 1000 patients with in average 13 sessions each. However, the NIRS experience will certainly allow a larger number of treatments with fewer sessions than 13. The centre will be built in a university and medical area, surrounded by scientific institutes. It will have its own equipment for medical imaging (CT scan, MRI, PET), contention making and of course treatment planning, but no inpatient facility relaying for that on the hospitals or hotels of the neighbourhoods. Anaesthesia possibilities for treating infants will be provided. Extensive out patient's consultation facility will be provided as well as data management possibilities. No chemotherapy delivery will be provided, relying for that on the surrounding medical facilities and in particular the large anti cancer centre of Lyon, located 5 minutes walking. A proton source will be included to make possible the availability of proton beams trough the carbon ions designed equipment. The use of protons will be devoted to paediatric patients and possibly to adults patients included in particular prospective trials comparing carbon ions and protons. However no specific equipment, except the proton source, will be added to the CIT in the final project. The centre will be operated with a staff of about 84 persons including only 8 MD (accounting for 6 full time practitioners) with a special status maintaining their links with their originating institutions, and preserving thus the fragile balance of medical teams we will have to face at that time due to the coming lack of physicians in France. Hopefully, close cooperation with others European places as Catalonia or Switzerland, for instance, will create a

fruitful stream of scientific and medical exchanges able to attract radiation oncologists and alleviate this expected staff shortening

CONCLUSION

So, as it can be seen, this comprehensive hadrontherapy project has gained its credibility through its sound scientific and medical programs. The inspiration and the

scientific support of NIRS in Japan and GSI in Germany along with the cooperation of the other European projects have been of great help, in particular for the medical aspects, which have been very sensitive in France. Therefore, ETOILE is continuing to look for tight scientific and medical cooperation with all the other hadrontherapy projects