

**The Ministry of Health of the Czech Republic
Bohumil Fišer
Minister of Health**

Prague,

20.06.2002

C.j. 13924/02

Dear Mr. Chairman,

I would like to take the opportunity to inform you that the Committee of the Ministry of Health has discussed and assessed the current state of the devitalisation of malignant tumours using the method of Dr. Foltyn at its session on the 17.06.2002. Its conclusions were based on the findings of a meeting held on the 16.04.2002 by the Academy of Sciences of the Czech Republic, the findings of the Czech Society of Allergology and Clinical Immunology, Czech Surgical Society and the Czech Society for Oncology. The Scientific Committee of the Ministry of Health concluded that the currently available results of experiments and the outcomes of the trial tests of devitalisation of malignant tumours do not permit us to continue with the trialling of this treatment method on patients.

I am enclosing the requested results of devitalisation surgeries of metastatic colorectal cancer and of metastatic malignant melanoma carried out at four sites authorised by the Ministry of Health to trial the devitalisation in clinical practice.

Kind Regards

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Enclosures: 2 pages

**Vážený pan
Luboš Olejář
Předseda svazu pacientů ČR
Sokolská 32
102 00 Praha 2**

A summary of results of devitalisation operations of metastatic colorectal cancer and of metastatic malignant melanoma as of 15.06.2002

I. Metastatic colorectal cancer

Four sites, Surgical Clinic of the Faculty Hospital Bulovka, The First Surgical Clinic of the General Faculty Hospital, the Institute of Experimental Medicine in Prague and Masaryk Institute of Oncology in Brno have been approved by the Ministry of Health to clinically test devitalisation of metastatic colorectal cancer. On the basis of the approved protocol and the informed consent of the patients, 25 patients, 9 men and 16 women, were treated with this method in the period from 01.03.2001 to 30.09.2001.

By 15.06.2001 20 (80%) patients were dead, 7 men and 13 women, the mean survival period following the procedure varied between 1-8 months.

Currently, 5 patients (20%) (2 women, 3 men) have been surviving for more than 8 months, for 3 out of them, there has been a substantial evidence of the progression of tumour, 1 patient has had a diagnosis of stable metastases in liver established, and 1 patient had lymph node metastases devitalised along in combination with excision of the primar tumor, no new metastases have appeared yet.

In none of the operations performed with the use of the devitalisation technique regression in measurable distinct metastases has been documented neither a significant improvement in the quality of life.

The devitalisation operations have not been found to be the causes of death in any of the cases. In 5 (20%) cases it was necessary to treat an infection in the operated area including a reoperation because of an inflammation of peritoneum.

II. Metastatic malignant melanoma

Three sites, Surgical Clinic of the Faculty Hospital Bulovka, The First Surgical Clinic of the General Faculty Hospital and Masaryk Institute of Oncology in Brno have been approved by the Ministry of Health to clinically test devitalisation of metastatic malignant melanoma. On the basis of the approved protocol and the informed consent of the patients, 26 patients, 11 men and 15 women, were treated with this method in the period from 01.03.2001 to 30.09.2001.

By 15.06.2001 it was not possible to evaluate the results of all the patients (24 patients) involved in the trials, as 2 patients failed to show up for further check ups after a progression of the tumour occurred following the devitalisation and we were not able to track whether they have deceased or are still alive. In the case of one of the patients the devitalisation treatment was performed twice on his own request within two months. Out of 24 patients, 21 (87%) that could be studied have already died (8 women, 13 men). The period of survival for the patients with a known date of death averaged between 1-11 months.

Up till now 3 (13%) patients are surviving 8 or more months after the operation with a progression of tumour.

We have been able to substantiate a long-term localised regression of devitalised metastases only in 3 patients, in 1 case a stabilisation of the diagnosis, albeit, the focuses of other metastases have been growing. In all the other instances, cancer has persisted or has been progressing, presumably having been partially sustained by diffusion from the surrounding tissue and peripheral revascularization.

In none of the operations performed with the use of the devitalisation technique a regression of measurable distinct metastases has been documented neither a significant improvement in the quality of life.

The performed devitalisation operations have not led to serious complications, however, 4 patients were diagnosed with an infection in the operation wound. These were treated conservatively.

Translated by: Mgr. Marie Urbancikova