FD in humans:

Fortyn and cal. describe six cases of performing FD in 1985. All the patients had GIT tumours and underwent the procedure in emergency when ileus or ileus like symptoms developed.

Four patients had a tumour located in different parts of colon, two had scirrhus carcinoma of colon.

The age of patients ranged from 57 to 82. The follow up varied from 4 to 7 years. Two patients had liver metastases, one had metastases in small intestine, one metastases in lymph nodes. There were not proven metastases in two patients. Two patients lived at the time of publication. Autopsy was performed in 2 patients. There were found no signs of a cancer disease in them. One patient died five years after FD without undergoing autopsy. Post operation fever, excretion of turbid fluid from the drains are mentioned as adverse effects (5).

Fortyn and cal. report one case of FD treated adenocarcinoma of the right kidney in 1987. No metastases were found. The patient was intended for excision of the tumour but this procedure had to be stopped rapidly for intraoperational cardiac arrhytmia and a decrease of blood pressure after the closure of hillar structures vessels and urethra. The patient recovered rapidly. He enjoyed a good health for three years when he died of cerebral haemorrhage caused by high pressure. No autopsy was done (13).

The last patient reported by Fortyn was a patient with ulcerated adenocarcinoma in 2001. The patient was operated in a state of diffused peritonitis 12 hours from the beginning of perforation of mediogastric ulcer carcinoma. The lady was 82 years old at the time of operation. The ischemisation of tumour was performed by a series of stitches placed over the whole periphery of carcinoma focus to avoid penetration. Stitching into the abdominal wall was done in a great distress and because any large defect of the stomach would have complicated the situation. She died 3 years later of vascular apoplexy. No autopsy is documented (11).

Kopsky elaborated a clinical protocol for the first phase of clinical trials in an attempt to confirm the feasibility of FD in 2010. He summarised the above mentioned cases by Fortyn except the last one in his protocol and reported new three cases (6). There is no available data about the testing or whether the testing was performed.

Newly reported cases by Kopsky include one case of adenocarcinoma of rectum and sigmoideum and two cases of melanomas.

The patient with adenocarcinoma in rectum and sigmoideum with metastases in liver was diagnosed during an explorative laparotomy which was followed by one dose of chemotherapy in the December of 2000. Chemotherapy was stopped since the patient was unable to bear it well. The tumour was devascularisated two months after this one dose of chemotherapy. There is of note that the patient was at the time of undergoing the FD so cachectic that he was unable to go to the bathroom. The patient was followed for 2 years. CT scans confirmed a progress in calcification of liver metastases. No new development of the disease was detected (6).

The first patient with melanoma underwent excision of primary tumour in the head area and its metastases in the right part of neck followed by adjuvant chemo- and radiotherapy in 1996. Lung metastases were found in 1997. Other excisions of melanoma were performed in 1997 and 1999. The patient underwent immunotherapy with interferon alfa in 2002. Melanoma of the size of 4 cm was devascularised in September 2002 when the patient had facial paresis and suffered pain. The pain was relieved 10 days after the FD. The patient was followed up for six months when a CT scan showed no development of cancer. The patient continued immunotherapy at that time.

The second patient had an excision of melanoma on her right foot in anamnesis. She underwent FD after metastases in lymph nodes were confirmed. The patient received immunotherapy at that time. There was done partial extirpation and partial devitalisation of the tumour. Histology showed an amelanotic melanoblastoma. Another partial devitalisation and partial devitalisation was performed in the same place two months later. She was followed

for next two years without any signs of cancer recurrence. The patient continued immunotherapy at the time of publication (6).

The method was approved for the first phase of clinical trials in 2001. The testing was performed in four oncological centres namely: Institut klinické a experimentální medicíny Praha (Institute of Clinical and Experimental Medicine in Prague), Všeobecná fakultní nemocnice v Praze (General University Hospital in Prague), Nemocnice na Bulovce (Bulovka Hospital in Prague) a Masarykův onkologický ústav v Brně (the Masaryk Memorial Cancer Institute in Brno). The trials were performed during 1.3-30.9.2001.

Results of the trials have not been published up till now. The only available brief summary of the testing is covered in a letter written by prof. M.D. Bohumil Fišer, at that time minister of health of the Czech Republic. The letter was an answer to the Patients Association requesting information about the trial and its results. The testing was performed in metastasing colorectal cancer and metastasing melanomas. There is no data about the previous therapy, history of the patients, the exact stage of the disease at the time of the trial. No data about performing autopsies is reported in the summary. Clinical protocols are not available either (7). It can be supposed that basic guidelines for the first phase of clinical testing were followed. This would mean that only terminally ill patients in whom conventional oncological therapy has been proven ineffective were considered and included (60).

The trials were performed in 25 patients with colorectal cancer, 9 women and 16 men and 26 patients with melanoma 11 being women and 15 men. The trials were evaluated up to the period of time 15.6.2002. None of the patient participating in the trials died in connection with the procedure. 5 cases of non specified infection complications in operated area are mentioned in the colorectal group. Among these complications is one case of peritonitis which required a surgical revision. This case of peritonitis is the most serious adverse effect mentioned for the both groups. No serious adverse effects are reported in the melanoma group. 4 cases of post operation infections in wound solved in a conservative way were reported in the melanoma group (7).

About 120 patients underwent devitalisation in line with WMA Declaration of Helsinki in other four institutions on their request outside of the trials (6).

The rise of body temperature, discard from the site of ligated tissue are commonly observed in cases in which there was FD performed in humans. It has been found that common analgesics do relieve the symptoms. Abdominal pain which mimics the beginning of peritonitis can observed in the cases where performing FD in the abdomen cavity as has been shown in the presented case study.

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60) Marta Munzarova, Lékařská etika v kontextu klinického výzkumu, Klin Farmakol Farm 2007; (21 3-4):125-127