

Pr BENELOUEZZANE Bourhane-Eddine
CHU Constantine - Faculté de médecine de Constantine –Algérie
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(recent prosthesis)

TREATMENT OF THE ANASTOMOSIS LEAKAGE
A NEW THERAPEUTIC CONCEPT
(POST OPERATIVE FISTULAS)
(PARAGRAPH 0064 to 0068 OF EUROPEAN PATENT)

The ruptures of digestive stitches, or post-operative digestive fistulas, represent a serious complication because of the metabolic and nutritive disorders that it engenders as well as the post-operative peritonitis which is often associated with it.

it is in fact a complication which can be found in *classical* as well as in *coelioscopic* surgery.

It can be observed in all levels of digestive tract, oesophagus, stomach, duodenum, small bowel, colon.

This complication may occur after any digestive operation .

Its incidence is of **1case / 11000 inhabitants**⁽¹⁾ with a resulting **mortality rate of 20 to 35 %** ^(1- 10) according to the published series.

Only 20 % of post-operative digestive fistulas heals without surgical re-intervention⁽³⁾.

The duration of hospital stay is long, it has been estimated to an **average of 71 days** (62 to 115) ⁽¹⁾ of which half , took place in an intensive health care unit.

The cost of health care has been evaluated in 1996 to 420 000 FF which corresponds to **63 000 Euros for a single patient** (1). It should be stressed that today a single day of hospital stay in intensive care costs around 1500 euros.

present therapeutic methods

- a. External deviation by a drainage tube
- b. Deviation by Jejunostomy or Ileostomy
- c. Deviation by Jejunostomy or Ileostomy
- d. Digestive exclusions
- e. The digestive resections
- f. The treatment with somatostatin (octreotide)
- g. Surgical treatment by artificial connective tissues⁽⁴⁾ .

These methods are not fully efficient, therefore the prognosis and the health care of this pathology have not known any considerable improvement.

THE PROPOSED METHOD

We have carried out research work which has enabled us to come out with a new therapeutic approach to anastomosis leakage.

This new therapeutic approach suggests the use of a prosthesis which we have conceived and patented.

Our method consists in realizing a direct and immediate repair of the digestive breach, as well as recreating the conditions for cicatrizing of digestive wound.

The method would have many advantages :

It is simple to be performed.

According to this new concept, our aims are:

- -to improve the treatment efficiency which up to now remains insufficient and not codified (present mortality rate around 30%).
- -to propose an appropriate therapeutic attitude which takes into account the difficulties and risks of early re-interventions; the treatment that we propose is rather conservative .
- -The patient's comfort ; because the proposed treatment will avoid to the patient the drawbacks of actual proceedings as enterostomies and long duration drainage.

- -the reduction of duration of hospital stay, which would according to our principle be inferior to 3 weeks (71 days with the present treatments)
- This represents a psychological advantage for the patient and a financial gain.
- -The reduction of health care costs:
- The expected **economy** would be of **40 000 euros per patient**.

Economical considerations

The management of anastomosis leakage is up to now very onerous.

Some data give us an idea about the economical interest of the project.

In USA ,The population is of 264 millions, the average number of cases is of 24000 per year (80% of these patients undergo a re-intervention) . In USA the cost of this pathology is of **1,2 Billiards USD** (1,2 Billiards of dollars) . Thus It would be, on many sides, very interesting, , to dispose of a method which includes many health care advantages as well as permits to make very important savings.

Pr BENELOUEZZANE Bourhane-eddine
 Service de Chirurgie générale 'A' CHU Benbadis
 Constantine 25000
 Faculté de médecine de Constantine 25000 Algérie
 E mail : borhaneddineb@yahoo.fr
 Tel 213 61 30 59 56 / 213 31 62 11 97 Fax 213 31 62 11 97

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