

# The Use of the Domestic Enzyme Preparation Pancreatin 8000 in the Rehabilitation of Patients with Chronic Pancreatitis After Surgery

## Wykorzystanie przygotowanego w warunkach domowych preparatu enzymatycznego Pankreatyna 8000 w rehabilitacji pacjentów z przewlekłym zapaleniem trzustki po zabiegu chirurgicznym

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### SUMMARY

**Aim:** To investigate the clinical efficacy of the domestic enzyme drug Pancreatin 8000 in the rehabilitation of patients with chronic pancreatitis after operations on the pancreas.

**Materials and Methods:** A study of 32 patients with chronic pancreatitis who received the drug Pancreatin 8000 (8000 Ipolytic Ph. U., 5800 amyolytic Ph. U. and 380 proteolytic Ph. U.) The course of treatment was 21 days. In the course of the study we evaluated the growth rate index (calculated by the formula:  $B/P - 100$ , where B is weight in kilograms, P is growth in centimeters) and data of clinical examinations. A pain syndrome was estimated by the nature, expressed and depending on a meal and daypart.

**Results:** In average, normalization of the frequency of vomiting was noted on the 2nd - 8th day, on the 8th day, vomiting in all the patients was once a day and formalized. Pain decreased and disappeared in the period from the 2nd to the 7th day. In 3 (7%) patients the pain did not decrease, that is why it was necessary to use pain-relieving drugs. The dynamics of body weight increase was from 1 to 4 kg during 3 months of taking the drug in different patients. No increase in body weight was noted in 1 (2%) patients. The disappearance of symptoms of gastrointestinal and intestinal dyspepsia was noted on the 2nd to 6th day.

**Conclusions:** Thus, the positive clinical effect of the drug Pancreatin 8000 is not only the result of the substituted enzyme therapy, but also the transition of the pancreas into a mode of functional calmness.

**Key words:** patients with chronic obstructive pancreatitis, Pancreatin 8000 enzymotherapy, dyspeptic syndrome, steatorrhea, postoperative rehabilitation

**Stowa kluczowe:** pacjenci z przewlekłym zapaleniem trzustki, enzymoterapia preparatem Pankreatyna 8000, zespół dyspeptyczny, stolce tłuszczowe, rehabilitacja pooperyacyjna

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### INTRODUCTION

Growth disease incidence Chronic pancreatitis (CP), ineffectiveness of therapy that is carried out, which often occurs, the development of important complications are the reasons for the pivotal attention of clinicians to this pathology [1],

Methods of surgical treatment currently used for pancreaticoduodenal zone diseases are often of palliative nature and do not always lead to restoration of adequate functioning of the intestinal and gastrointestinal tract, to restoration of quality of life of the patients [2],

The main clinical symptoms of chronic pancreatitis are, first of all, pain syndrome, disorders of trauma associated with

external secretory deficiency of the pancreatic gland (PG), disruption of the function of the insular apparatus, biliary deficiency syndrome.

Not all cases (CP) can be treated surgically. In 70% of patients it is possible to achieve the least time-consuming treatment, which does not affect the quality of life of the patient. This is achieved through conservative treatment. When the arsenal of conservative treatment approaches is exhausted and no effect is achieved, surgical treatment is considered [3]. In the last years most surgeons give preference to various organ-sparing surgeries [5]. In this case, the problem of preserving the duodenum (D) as the most important sensory, regulatory and endocrine zone in

surgical treatment of chronic pancreatitis is the most important [6].

Exosecretory function of the pancreatic gland plays a key role in the maintenance of intestinal traumatization as the main component of the traumatic pathway due to the unique multisubstrate set of hydrolytic enzymes in the pancreatic secretion.

Therefore, in case of secretory pancreas deficiency, a substitute enzymotherapy is indicated. It corrects and replenishes the lack of intestinal digestion and the resulting lack of absorption of primary micronutrients from the small intestine, leading to an authentic transformation of intestinal microflora. Regulatory properties of pancreatic enzymes are essential in their use not only to replace the lack of digestion but also to put pancreas into a reduced secretory activity mode, especially on an empty stomach [7,8].

### AIM

Taking into account the current state of the problem of chronic pancreatitis treatment the development of pathogenetic substantiation of enzyme therapy schemes in patients with surgical diseases of pancreas during the period of postoperative rehabilitations was developed.

### MATERIALS AND METHODS

We studied 32 patients with chronic complicated pancreatitis who received Pancreatin 8000 (8000 lpolytic Ph. U, 5800 amylolytic Ph. U. and 380 proteolytic Ph. U.) The treatment course was 21 days. In the course of the study we evaluated the growthrate index (calculated by the formula:  $B/P - 100$ , where B is weight in kilograms, P is growth in centimeters) and data of clinical examinations. Pain syndrome was evaluated according to its character and severity, depending on the period and time of the day.

Pancreatin 8000 has an acid-proof membrane that protects enzymes from inactivation by the gastric juice, which makes it possible to use Pancreatin 8000 without combining it with drugs that reduce the action of hydrochloric acid [8].

Only under the influence of neutral or mildly acidic medium of the small intestine the coating is liquefied and enzymes are eliminated. Maximum enzymatic activity of the drug is detected 30-45 days after oral administration. Characteristics of this group of patients are given in Table 1.

The operations are carried out using modern technologies.

### RESULTS

In the course of the study we evaluated the growth-vaginal index (calculated by the formula:  $B/P - 100$ , where B is weight

in kilograms, P is growth in centimeters) and data of clinical examinations.

Pain syndrome was evaluated according to its character and severity, depending on the food and the time of day. The number and type of pain medications taken by the patients and their efficacy were noted. Dyspepsia syndrome was assessed by The following symptoms: heavy epigastric pressure after eating, nausea, vomiting, abdominal deflating, flatulence. In patients with chronic pancreatitis who have developed cysts After minimally invasive surgical intervention (external drainage of the bone under ultrasound control) the number and quality of the species were assessed Frequency, quantity, character of feces at the stages of enzymocorrection were assessed, the quantity of neutral fat in feces was determined by microscopy.

In all patients with complicated chronic pancreatitis the degree of external secretory deficiency of pancreas was assessed as important: All the patients had marked pain after meals, heaviness in the region of the stomach, nausea, flatulence, poor feces from 3 to 6 times a day, the growth-volume index was 0.75-0.82. The acidic coating of the tablets protects the enzymes from inactivation by the gastric juice. Only under the influence of neutral or mildly acidic medium of the small intestine the coating is liquefied and the enzymes are eliminated. Maximum enzymatic activity of the drug is recognized 30-45 days after oral administration.

According to ultrasound investigation, all patients had signs of diffuse changes of pancreas, manifested to some extent or other, increased size of the gland, its increased echogenicity on ultrasound examination. The efficacy of Pancreatin 8000 in patients with pancreatic cysts alter external drainage allows recommending it also in the postoperative period for adequate preparation of patients for the next stages of surgical treatment. We used Pancreatin 8000 orally 1 capsule 3 times a day during meals.

In average, the normalization of the rhythm frequency was noted on the 2nd-8th day, on the 8th day, the rhythm in all the patients was once a day and formed. The pain decreased and disappeared in the period from day 2 to 7. In 3 (7%) patients the pain did not decrease, that is why it was necessary to use pain-relieving drugs. The dynamics of body weight increase was from 1 to 4 kg during 3 months of taking the drug in different patients. In 1 (2%) of the patients

No increase in body weight was noted. Symptoms of gastric and intestinal dyspepsia disappeared on the 2nd to 6th day.

Table 1. Characteristics of the examined patients

Groups of patients studied	Age of patients (years)	Examination of the patients
Chronic pancreatitis with exocrine insufficiency.	32 to 54	15
Ultrasonic drainage of pancreatic cysts glands.	22 to 61	13
Pylorusparing pancreaticoduodenal resection.	36 to 41	1
Medial resection of the body pancreas	35 to 52	2
Resection of the head of the pancreas with preservation , of the duodenum		
Total:		32

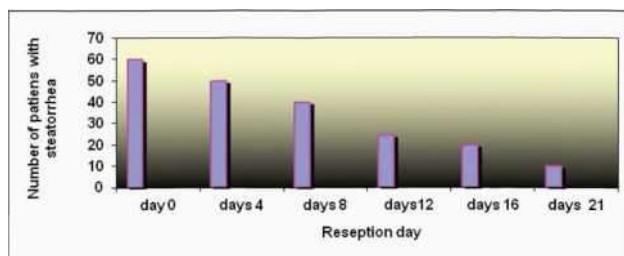


Figure 1. The results of the coprological examination

After normalization of these indices, the dose was gradually reduced: to 5-11 days - 2 capsules per day, to 15-18 days - 1 capsule per day. In the meantime, Pancreatin 8000 was used only when necessary. No reversion of clinical manifestations of external insufficiency was noted. The results of the coprological examination are shown in the Figure 1.

Dynamics of changes in the amount of neutral fat in the feces, assessed by coprological examination, and the efficiency of steatorrhea reduction in patients with chronic pancreatitis on the background of receiving Pancreatin 8000.

In all chronic pancreatitis patients the degree of steatorrhea was assessed as important (3 units). By the 21 st day of treatment with Pancreatin 8000 the steatorrhea completely disappeared.

Taking into account the results obtained, it can be argued that the clinical effects of the course intake of Pancreatin 8000 are due to the fact that Pancreatin 8000 contains physiological doses of enzymes. Acidic coating of the tablets protects the enzymes from inactivation by the gastric juice. Only under the influence of neutral or mildly acidic medium of the small intestine, the coating is liquefied and the enzymes are eliminated. Maximum enzymatic activity of the drug is recognized 30- 45 days after oral administration.

We dynamically monitored patients who underwent surgeries on the pancreas and perampullary zone from the beginning of their food intake, and inpatients chronic pancreatitis complicated by cysts, after external drainage under ultrasound control, biochemical and cytological examination of the intracellular contents on drains, i.e. after establishment of the nature of the secretion.

The comparative characteristics of the clinical effects of Pancreatin 8000 course treatment in patients who underwent different types of surgical interventions on the pancreatoduodenal area are presented in Table 2.

As we can see from Table 2, the effectiveness of the enzymotherapy depends on the volume of the surgical intervention oil the pancreas. Pain syndrome decreased for the shortest period in patients who underwent cyst drainage under ultrasound control and resection of the pancreas head with preservation of the duodenum.

Pain syndrome persisted for a long time in patients after pylorus-preserving pancreatoduodenal resection (PPPDR). The frequency of stylostomy was normalized in short terms in patients after cyst drainage. Symptoms of gastric dyspepsia when receiving Pancreatin 8000 at the shortest possible time were cured in patients after medial resection of the pancreas body (MRPB), intestinal dyspepsia - in patients who underwent bone drainage under ultrasound control.

The number of drainage diluents from the pancreas ranged from 70 ml to 300 ml. In 85% of the patients, the amount of the fluid decreased by half to 11 -17 days. During the follow-up period the amount of liquid in the drains tended to decrease only in 12% of the patients (Figure 2).

The time frame for decreasing the dose of the drug varied. Thus, the highest number of 3 capsules per day was taken by patients who had experienced (PPPDR). The above results of the study allow us to conclude that the substituted and corrosive therapy of external secretory deficiency of pancreas after surgical treatment with the enzyme preparation Pancreatin 8000 leads to the restoration of adequate functioning of the pancreaticoduodenal apparatus.



Figure 2. Clinical effects of using Pancreatin 8000

Table 2. Clinical effects of tertiary treatment with Pancreatin 8000 in chronic pancreatitis patients in the postoperative period

Types of operatios, parameters	Drainage ofthe crusts under ultrasonic control	Resection ofthe body ofthe pancreas	PSPDR	Resection ofthe head ofthe TZ witlpreservation DFS
Increaseinweighttela	1,5-4,5 kg	2,1-3,2 kg	3,2 kg	1-3 kg
Buying pain syndrome	2-5 days	4-6 days	3-7 days	4-6 days
Buying Gastric dyspepsia	2-6 days	2-4 days	34 days	2-4 days
Copied from intestinaldyspepsia	2-4 days	4-5 days	5-7 days	4-6 days
Change doses up to 2 capsules peidey	6-9 days	8-10 days	9-12 days	7-8 days
Dose reduction to 1 capsules indey	13-15 days	15-18 days	17-20 days	16-17 days

## DISCUSSION

Taking into account the current state of the problem in the treatment of patients with chronic pancreatitis, the work is aimed at the development of pathogenetic treatment regimens for patients with surgical diseases of the pancreas during the period of postoperative rehabilitation [1,3].

The main goal of substitution therapy with pancreatic enzymes is to ensure sufficient ligase activity in the duodenum. It is known that the influence of hydrochloric acid on pancreatic enzymes leads to destruction of up to 90% of their quantity, that is why the way to undermine the gastric acid barrier was the creation of galenic forms of polyfenmental preparations in the acid-stable lining [6,8].

The use of the drug that has such a film increases fat absorption by 20% on average compared to a comparable dose of pancreatin without the film [4, 5], Indications for substituted enzyme therapy in chronic pancreatitis with external hypersecretory deficiencies [8]:

Steatorrhea with a fecal loss of over 15 g of fat per day;

Progressive trophologic deficiency;

Stable diarrheal syndrome and dyspeptic complaints.

A fundamentally important aspect of enzymotherapy is that it inhibits the stimulating pancreatic secretion, which is expressed in the body of Pancreatin 8000. We consider it important that galvanizing the secretion of the gland, giving it "functional exosecretory rest" can contribute to regenerative processes in the damaged organ.

Positive clinical effect of using Pancreatin 8000 is not only the result of substitutive enzymotherapy, but also the result of putting the pancreas into its secretory minimization mode, supported by Pancreatin enzymes galumphant 8000 with duodenum. This complex mechanism should explain the efficacy of the treatment of Pancreatin 8000 in patients with a complicated course of chronic pancreatitis. The dosage of Pancreatin 8000 must be administered on an individual basis.

In a number of cases in important patients, it is reasonable to increase the dosage of Pancreatin 8000 to 5-10 capsules per day. The efficacy of Pancreatin 8000 inpatients with pancreas cysts after external drainage allows recommending it also in the preoperative period for adequate preparation of patients for further stages of surgical treatment

## CONCLUSIONS

Thus, the positive clinical effect of using Pancreatin 8000 is the result not only of substitutive enzymotherapy, but also of putting the pancreas into a mode of functional calmness.

The efficacy of substitution therapy depends on the volume of surgical intervention on the pancreaticoduodenal complex. Dosage of Pancreatin 8000 must be administered on an individual basis.

In a number of cases in important patients, it is justified to increase the dosage of Pancreatin 8000 to 5-10 capsules per day.

The efficacy of Pancreatin 8000 in patients with pancreas cysts after external drainage allows recommending it in the preoperative period for adequate preparation of patients for further stages of surgical treatment.

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### Conflict of interest:

The Authors declare no conflict of interest

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