

# Cost-effectiveness of benign Wirsung duct strictures treatment in chronic pancreatitis

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## Abstract

**Introduction:** Chronic pancreatitis (CP) is an important problem for modern medicine, the healthcare system (Poland – NFZ) and the national insurance system (Poland – ZUS). The chronic nature of the disease, the lack of targeted treatment and the low mortality rate lead to an accumulation of patients who demand expensive treatment, both conservative and invasive. Rising costs in health care are forcing the need for a more cost-effective method of treatment.

**Aim:** The primary aim of this study was to perform a retrospective calculation of costs in both surgical and endoscopic treatment, hospital stay, healthcare, and public insurance of patients suffering from chronic pancreatitis. Parallel quality of life analysis was performed. It was possible to develop a cost-effective therapeutic algorithm for patients with an uncomplicated stricture of Wirsung's duct within the Polish health care system.

**Results:** In Poland, the hospital costs of endoscopic treatment of patients with chronic pancreatitis were higher than those of the surgical treatment group despite both resulting in a similar life quality.

**Conclusions:** From a cost-effectiveness perspective, it was shown that surgical intervention is a more cost-effective therapy than endotherapy. Furthermore, patients with benign stricture of the main pancreatic duct in chronic pancreatitis should not be treated with endotherapy for longer than 12 months.

**Key words:** chronic pancreatitis, endotherapy, surgical drainage procedures, Wirsung duct stricture, cost-effectiveness.

## Introduction

Chronic pancreatitis (CP) is a major concern from the point of view of modern medicine, the health care system and the social security system. The Polish population has approximately 2,000 new cases of CP every year [1, 2], mostly among men at the peak of productive age (35–50 years), in most cases patients smoking and abusing alcohol [3–5]. The chronic nature of the disease and low mortality lead to the accumulation of patients requiring expensive treatment, both conservative and invasive (endotherapy, surgery) [6]. One of the most important clinical problems of CP is that modern medicine has no causative

treatment of CP, since both endotherapy and surgical treatments are only symptomatic treatments [7].

The European Society of Gastrointestinal Endoscopy (ESGE) issued a recommendation (Level B) that endoscopic treatment should be the first line treatment in uncomplicated cases of chronic pancreatitis with pain syndrome. A high efficacy of endoscopic drainage has been shown (75–94%) [8–14]. In the case of an unsatisfactory effect further treatment should be discussed by a multidisciplinary team (endoscopist, surgeon and radiologist). In this situation, surgical treatment should be considered, especially if the patient can be expected to have little chance of a sustained response to endotherapy [15]. This

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position is also confirmed in the recommendations of the American Society for Gastrointestinal Endoscopy (ASGE) of 2006 [16].

On the basis of those standards [15, 16] and also Polish Pancreatic Club recommendations, the wrong conclusion should not be made about the rivalry between endotherapy and surgical treatment of drainage as a method of choice in CP. With these recommendations, it is possible to select patients who will achieve greater benefit from endoscopic than surgical treatment [17].

There are a number of data on surgical and endoscopic treatment of CP and guidelines for conduct. Unfortunately, there are only a few reports of a comparative character for both methods and evaluation of the cost-effectiveness ratio [18–22]. The ratio of treatment costs to the quality of life and the real burden on the health care system associated with surgery and endotherapy is also not known. The author of this paper sees a gap, which was established in connection with the changes in the Polish health care system and the ongoing crisis in the social insurance sector. The operations reforming the health care system in Poland are aimed at optimizing the cost of treatment. In other health systems the monitoring of the treatment in the context of cost efficiency and trying to estimate the cost-effectiveness relationship of two main algorithms in invasive treatment of CP is introduced. In Poland there is no comprehensive study which would allow one to refer the data to the specificity of the Polish health care system.

### Aim

The scope of the paper is to determine the cost of surgical and endoscopic treatment in patients with chronic pancreatitis, for the hospital, the health system and the social security system in Polish con-

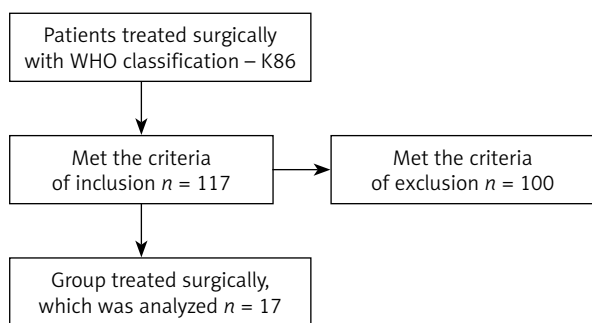
ditions. A further aim is to establish an algorithm for dealing with patients with uncomplicated stenosis of the Wirsung duct in the course of CP in the reality of the Polish health care system based on the treatment cost-effectiveness ratio.

### Material and methods

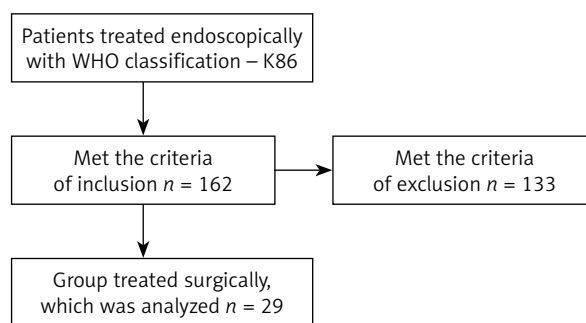
The retrospective study analyzed direct and indirect costs of treatment of patients with CP hospitalized at the University Clinical Center (UCC). All patients with ICD10-K86 diagnosis and hospitalized in UCC in the years 2006–2011 were checked. In order to select a uniform and homogeneous group the following criteria for inclusion and exclusion from the study were used.

Criteria for inclusion in the analysis: CP – onset of treatment in the years 2006–2011, confirmed diagnosis of CP (history, imaging studies), objectively confirmed Wirsung duct stenosis on CT, ultrasound or endoscopic retrograde cholangiopancreatography (ERCP), confirmation of stenosis during the first session of endotherapy; hospitalization in the Department of Gastroenterology and Hepatology of the Medical University of Gdansk associated with pancreatic endotherapy or at the Department of General, Endocrine and Transplant Surgery, Medical University of Gdansk associated with drainage or drainage-resection surgery (pancreatojejunostomy according to Puestow, Frey or Bern).

Criteria of exclusion: previous surgical procedures on the pancreas; endoscopic or surgical treatment of pancreas outside the center of the trial; suspected tumor of the pancreas; diagnosis of bile duct or duodenal stenosis in the course of CP; age < 18 and > 65 years (outside of productive age); follow-up period of less than 1 year; previous analgesic surgical treatment (splanchnicectomy, alcohol injection



**Figure 1.** Group treated surgically – selection scheme of the study group, treated surgically



**Figure 2.** Group treated endoscopically – selection scheme of the study group, treated endoscopically

into celiac plexus); incomplete documentation – no data for medical costs calculation (Figures 1, 2).

In calculating the direct costs for the hospital, cost of drugs, diagnostics (imaging and invasive), consultations, the cost of the operating theater, anesthesia costs, hospital overhead administrative costs and the final income of the hospital were taken into account.

Analysis of indirect cost was based on an assessment period of sickness absence (only for disease entity – K86) and the number of days of allocated pensions due to sickness incapacity for work (the main cause of incapacity – K86), rehabilitation benefits from social insurance, helplessness allowances from social insurance, unemployment benefits paid by the Labor Offices (LO) and the benefits provided by the Municipal Social Assistance Centers (MSAC), and thus the costs for the social security system, social welfare and labor offices.

The costs incurred by the healthcare system (NFZ) were calculated as the sum of medical procedures. In order to standardize settlements with the National Health Fund (NFZ) the value of the hospital reimbursement point applied in October 2011 was set (direct costs were charged in accordance with the prices in force in the UCC during this period).

Quality of life was assessed after the end of the 3-year follow-up period using three validated tools [23–28]. The form proposed by Bloechle and Izbicki was used [29]. Izbicki score – a factor of Izbicki, EQ-5D-5L with EQ-VAS (1990 EuroQol Group. EQ-5D – EuroQol Group) [30] and SF-36 (1992 MOS: 36 item Short Form Health Survey RAND Corporation) [31].

For the evaluation of treatment complications a six-level DeOliveira scale was used [32].

In this paper, a “cost of illness (CoI)” analysis was carried out. The cost of disease and cost-effectiveness (CEA) on the basis of direct costs (hospital) and indirect costs (sick leave, pension, reimbursement of medicines, etc.) was summarized with the quality of life determined by the SF-36, EQ-5D and Izbicki score. Data on the costs after the first year of treatment and at the end of the 3-year observation period were compared with the quality of life assessed at the beginning of observation.

### Statistical analysis

In descriptive analyses indicators of the structure, means and standard deviations were used. In comparative analyses Student’s *t*-test, the  $\chi^2$  test and the Mann-Whitney test were used. Analysis of variance was performed using ANOVA and the post-hoc Scheffe test. Statistical significance was accepted at  $p < 0.05$ . Statistical analyses were performed using Statistica commercial software.

## Results

### Population

Analyzed groups contained 29 patients treated endoscopically and 17 who underwent surgery. There were no statistically significant differences between groups in demographic structure or disease stage (Tables I, II).

### Total hospitalization costs

Total hospital costs (cost of hospital stay, medical procedure related costs, medications, diagnos-

**Table I.** Demographic structure and distribution of the etiology of CP in study groups with the level of statistical significance, the odds ratio and 95% confidence interval

Parameter	Group treated endoscopically	Group treated surgically	P-value
Number of patients	29	17	
Mean age at start of treatment [years]	48.7 ±10.4	46 ±8.8	0.3
Gender M/F	11/18 (38%/62%)	5/12 (30%/70%)	0.6
Duration of CP before treatment [years]	5 ±5.2	7.5 ±4	0.08
BMI at start of treatment	22.3 ±3.5	22.2 ±3	1.0
Alcohol etiology	15 (52%)	9 (53%)	0.9
Biliary etiology	6 (21%)	1 (6%)	0.2
Unknown etiology/unspecified	8 (27%)	7 (41%)	0.3

**Table II.** Comparison of treatment groups in terms of pancreatic insufficiency, pain intensity and consumption of analgesics before treatment

Parameter (prior to treatment)	Group treated endoscopically	Group treated surgically	P-value
Diabetes type 3	14%	35%	0.09
Need of insulin therapy	10%	29%	0.11
Need of pancreatic enzyme supplementation	100%	94%	0.3
Daily dose of pancreatic enzyme [thousands of units]	62.46	67.94	0.3
Presence of severe pain	56%	86%	0.06
Subjective assessment of pain VAS score	2.12	3.64	0.18
Received amounts of morphine equivalents	2.24	3.43	0.18

tics costs, etc.) after the first year of treatment did not differ significantly between the two treatment groups and were €2660 (10 470 zł) for the endotherapy group and €2550 (10 050 zł) for the surgical drainage group ( $p = 0.794$ ). The cumulative average total cost of the endotherapy group after 3 years of treatment was €4257  $\pm$ 2000 (16 773  $\pm$ 7877 zł (zł = Polish Zloty), while in the surgical group it was €2879  $\pm$ 1288 (10 049  $\pm$ 5077 zł) ( $p = 0.002$ ). The longitudinal analysis showed a significant cost difference with the duration of treatment in the endoscopic group (ANOVA  $p < 0.001$ ). The first year of treatment was the most expensive in both groups ( $p < 0.001$ ) compared to the 2<sup>nd</sup> and 3<sup>rd</sup> one.

### Procedure related costs

Endotherapy costs were related to a wide range of treatment options and different number of disposable equipment; the cost ranged from €123 (486 zł) to €719 (2510 zł) for a single procedure. The average cost of one procedure calculated on the basis of the real costs was €360  $\pm$ 90 (1418  $\pm$ 314 zł). The longitudinal analysis of the endoscopically treated group showed a significant decrease in costs of endotherapy after the first year of observation (ANOVA  $p < 0.001$ ). In the first year of treatment, costs were the highest (ERCP sessions every 3–6 months) and the difference in costs between the 3 observations was significant.

The costs of the operating theater equipment and anesthesia were charged in the surgical drainage procedures group. The average cost was €268

$\pm$ 75 (1056  $\pm$ 295 zł) for a single procedure. Time of operating procedures ranged from 2 h 30 min to 9 h, and amounted to an average of 4 h 15 min  $\pm$ 1 h 40 min. The total cost of intervention averaged €460  $\pm$ 175 (1814  $\pm$ 688 zł) per hospitalization.

### Other costs

There were no significant differences between out-of-hospital drug costs in the group treated endoscopically and surgically both after the first year and the end of the 3-year observation period. The costs of laboratory tests in the endoscopically treated group were significantly higher both in the first year of therapy and at the end of the third year of the follow-up ( $p < 0.05$ ). The total cost of diagnostic imaging is statistically significantly lower in the group treated surgically €37 (144 zł) in comparison to patients treated endoscopically €107 (420 zł).

### Number and length of hospitalizations

The average number of hospitalizations in the group treated endoscopically was higher than in the surgically treated group ( $p < 0.001$  for all comparisons) (Table III).

The cumulative number of hospitalization days (Table IV) was statistically significantly lower in the group treated surgically than in the group treated endoscopically, both after the first year of therapy and at the end of the 3-year follow-up.

Longitudinal analysis of the endoscopically treated group showed a statistically significant decrease in the mean number and length of hospi-

**Table III.** Average number of hospitalizations in the study groups

Hospitalization	Group treated endoscopically	Group treated surgically
First year of treatment	2.79 ±1.10	1.17 ±0.52
Second year of treatment	1.73 ±0.72	No hospitalizations
Third year of treatment	1.44 ±0.61	No hospitalizations
Mean number of hospitalizations per year during follow-up	2.08 ±0.96	0.53 ±0.17

**Table IV.** Cumulative average length of hospitalization in both groups

Variable	Average length of hospital stay [days]		P-value
	Endoscopic treatment	Surgical treatment	
In the first year	17.90 ±11.75	11.47 ±7.84	0.049
After 3 years	25.97 ±16.02	11.47 ±7.84	0.001

talizations with subsequent years of observation (ANOVA  $p < 0.001$ ). In the first year of treatment, the number of hospitalizations per patient was the highest ( $p < 0.001$ ) and the stays were the longest ( $p < 0.001$ ).

**Complications**

The incidence of method specific complications (endotherapy: post-ERCP pancreatitis or readmission because of exacerbation of CP during endotherapy = 10, surgery: CP exacerbation in post-operative period  $n = 1$ ) and nonspecific (endotherapy: intra-abdominal infection not related to pancreas  $n = 2$ , urinary tract infections  $n = 1$ , peptic ulcers = 1, limb ischemia = 1, surgery: wound infection  $n = 3$ , sub-

cutaneous hematoma  $n = 1$ ) showed no statistically significant differences between the two groups. Also the assessment of the severity of nonspecific complications by the DeOliveira scale did not show significant differences. We observed a statistically higher severity score of specific complications in patients treated endoscopically (Table V).

**Quality of life**

Assessment of global quality of life assessed by the EQ-5D questionnaire showed no significant differences between the two groups. The results of the analysis of the EQ-5D VAS questionnaire showed significantly higher satisfaction with the health status in patients treated surgically.

**Table V.** Mean number and DeOliveira score severity method specific and nonspecific complications per hospitalization in first year and after 3 years of treatment

Complications – DeOliveira Score		Mean DeOliveira Score		P-value
		Endotherapy	Surgical treatment	
Number of nonspecific complications per hospitalization	1 <sup>st</sup> year	0.14 ±0.44	0.24 ±0.44	0.472
	After 3 years	0.17 ±0.65	0.24 ±0.47	0.654
Number of method specific complications per hospitalization	1 <sup>st</sup> year	0.28 ±0.65	0.06 ±0.24	0.191
	After 3 years	0.28 ±0.19	0.06 ±0.65	0.191
DeOliveira score of nonspecific complications per hospitalization	1 <sup>st</sup> year	0.17 ±0.60	0.35 ±0.79	0.386
	After 3 years	0.17 ±0.39	0.35 ±0.60	0.386
DeOliveira score of method specific complications per hospitalization	1 <sup>st</sup> year	1.02 ±1.00	0.18 ±0.53	< 0.001
	After 3 years	1.74 ±1.68	0.18 ±1.68	< 0.001

Between the groups treated endoscopically and surgically there was no significant difference in the Izbicki score.

The two treatment groups did not differ significantly in terms of the summary index of physical health. Statistical analysis of the summary index of mental health (MCS) and its components did not detect significant differences between the two study groups.

### Treatment cost-effectiveness

The cost of a potential increase of pain treatment quality based on the questionnaire EQ-5D VAS value by 1% for the group treated endoscopically after 3 years of follow-up was €83 (328 zł). In the surgically treated group, this cost was €37 (145 zł) (Figure 3).

The cost of a potential increase of the questionnaire EQ-5D value by 1% for the group treated endoscopically after 3 years of follow-up was €63 (247 zł). In the surgically treated group the cost was €31 (123 zł) (Figure 4).

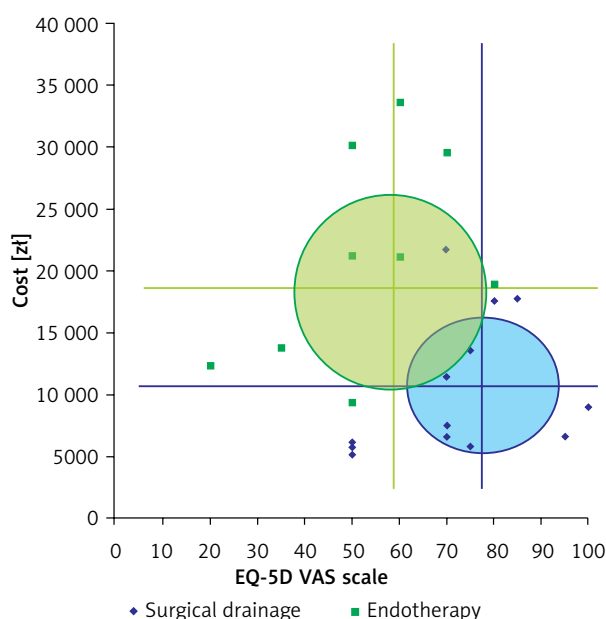
The cost of a potential decrease in the value of Izbicki's factor by 1% for the group treated endoscopically after 3 years of follow-up was €156 (613 zł). In the surgically treated group the cost was €110 (436 zł) (Figure 5).

The cost of a potential increase in the value of the SF 36 PCS factor by 1% of the group treated endoscopically after 3 years of follow-up was €72 (286 zł). In the surgically treated group, the cost was €36 (143 zł) (Figure 6).

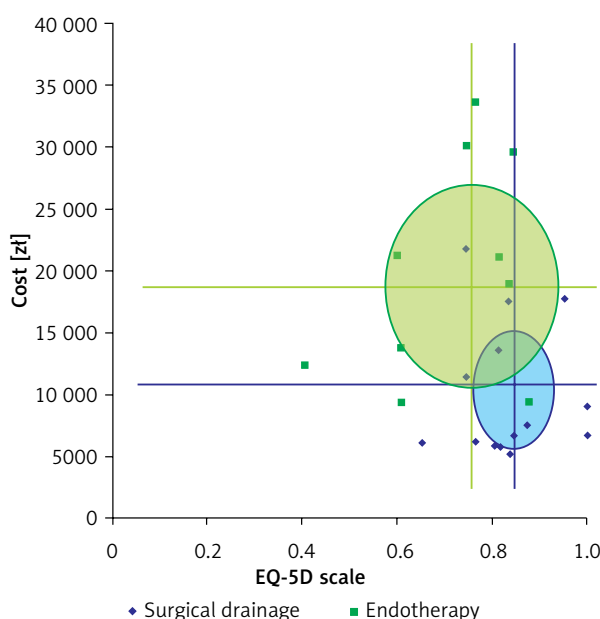
### Health care system costs

From the perspective of the 3-year follow-up surgical treatment generates an income for the hospital at approx. 40% of the sum appraised by the National Health Fund (NFZ), while the endoscopic treatment gives an income of 20% of the given amount. The difference reaches the threshold of statistical significance ( $p = 0.042$ ). The group treated endoscopically receives significantly higher income from the National Health Fund compared to the group treated surgically, but with significantly higher hospital costs.

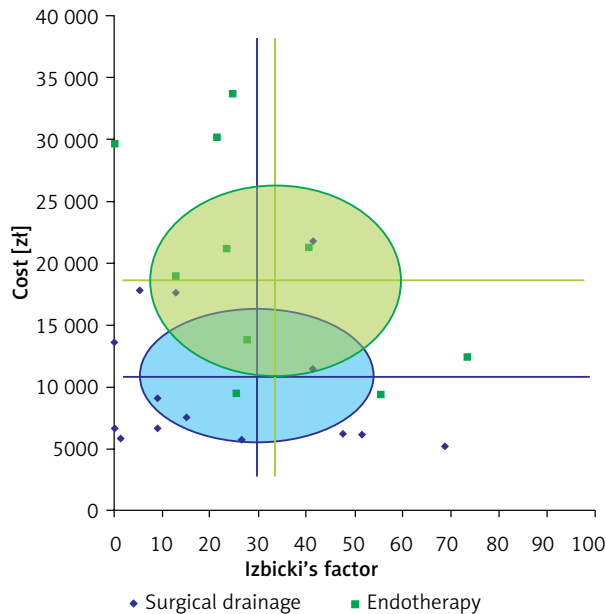
The cost of the surgical procedure from the perspective of the payer (NFZ) was after the first year significantly higher. After a 3-year observation period the expense borne by the NFZ was significantly higher in the group treated endoscopically. After taking into account the cost of drug reimbursement (higher in the surgical group, because in Poland patients after any kind of pancreatic tissue resection have full supplementary payment for pancreatic



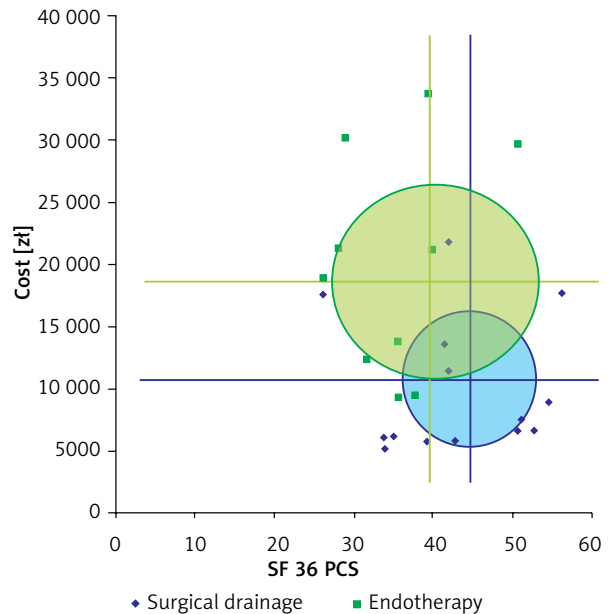
**Figure 3.** Accumulated cost to quality of life (EQ-5D VAS scale) after 3 years of follow-up in both study groups



**Figure 4.** Accumulated cost to quality of life (EQ-5D scale) after 3 years of follow-up in both groups



**Figure 5.** Dependence of the accumulated cost to quality of life (Izbicki's factor) after 3 years of follow-up in both study groups



**Figure 6.** Dependence of the accumulated cost to quality of life (SF 36 PCS) after 3 years of follow-up in both study groups

enzymes supplementation, but after endotherapy patients have to cover this expense), the difference between the study groups was no longer significantly different.

Patients undergoing drainage procedures rarely took any pensions due to inability to work, slightly more often used the help given by Municipal Social Assistance Centers (MSAC) and received an unemployment allowance, and also had lower sick leave absence (113.25 vs. 57.33 days), but none of the differences reached the level of statistical significance. The cumulative cost of all social benefits in the 3-year observation period was lower in patients treated surgically than in patients treated endoscopically (€2500 vs. €4050; 9852 zł vs. 15 954 zł,  $p = 0.151$ ). This relationship does not reach statistical significance.

## Discussion

With limited funds for health care and year-to-year shrinkage of the Social Insurance Institution budget, CP is becoming a serious socioeconomic problem. Studies have shown that the percentage of patients with CP treated invasively, unable to work, has increased with time from 6% to 40% and in conservative treatment exceeds 50% [33–35]. Similarly, in this study, the proportion of people unable to

work was more than 30%. The majority (70–90%) of patients were given social benefits (permanently or temporarily) due to illnesses of various kinds. Effectiveness of endotherapy has already been proved, but prolonged endotherapy in chronic pancreatitis is still under discussion [36–38]. In Japanese studies hospital costs, number and length of hospitalizations associated with endotherapy and surgical treatment (mainly Frey operations) were compared [22]. The study was conducted on two study groups of 34 patients. During the first year of follow-up Hirota *et al.* noted that the cost-effectiveness of treating patients surgically and by “short implantation” (end of treatment until one year) do not differ from each other. The group which required prolonged endotherapy, already during the first year of treatment showed higher medical costs, and longer and more numerous hospitalizations. Hence, in the case where due to the clinical picture the endotherapy extended over 1 year, a decision on the choice of treatment that is more favorable financially – in this case surgery – should be made [22]. In this study, the total cost incurred by the hospital in the first year of treatment, both surgical and endotherapy, did not differ significantly. Patients treated with endotherapy were sent to the hospital significantly more often ( $p < 0.05$ ), and their total hospitalization was

longer ( $p < 0.05$ ). The lack of difference is a result of the significantly higher cost of staying on a surgical ward. Therefore, even though the annual amount of days of hospitalization of patients treated with surgery is lower, the cost is similar to the group treated endoscopically. Longer hospital stay in the endotherapy group may be caused by readmissions because of exacerbations of CP during endotherapy, and if we consider the small number of analyzed cases it may influence the cumulative length of hospitalization. It is worth mentioning that the outlay of the Japanese health care system, although proportional to the Polish one, was 4 times higher (€2657 vs. €12 156 (10 467 zł vs. 47 894 zł) for the endotherapy group and €2550 vs. €8525 (100 49 zł vs. 33 588 zł) for the surgical drainage group). It is similar as regards the number and length of hospitalization. It follows that both the treatment regimen and average costs differ from Polish conditions and cannot be directly transferred to our situation. The strategy of treatment, hospitalization time and interval between hospitalizations in Polish conditions are determined not only by medical grounds, but also the principles of the financing of medical services by the National Health Fund, which complicates a fair comparison of treatment strategies in other health care systems.

The work of Laramée *et al.* [19] based on a randomized clinical trial of Cahen *et al.* compares the cost of endoscopic and surgical treatment from the point of view of the British health system (NHS UK) [20, 21]. The work was commissioned for the needs of the National Institute for Health and Care Excellence (NICE) in order to create an analysis based on the cost effectiveness in treatment of CP in the UK. After taking into account the quality of life Laramée *et al.* obtained a statistically significant favorable cost-effectiveness ratio for surgical treatment in comparison to endotherapy for both the 2- and 6-year follow-up period. Unit costs of a surgical procedure, as well as the percentage of complications, which is associated with expensive treatment and loss of quality adjusted life years (QALYs), are found to be significantly lower than the total cost and the loss of QALYs in multiple endoscopic sessions [19]. Similarly, in this analysis, the potential costs associated with increased quality of life, irrespective of the assessed scale, were higher in the endotherapy group, wherein the difference between the group treated surgically and the group treated endoscopically increased with time. Laramée *et al.*

did not take into account the cost of post-hospital care, the decline in productivity and periods of incapacity to work, recognizing that with a high degree of probability both parameters are favorable for the group treated surgically, especially in the long-term follow-up.

Despite minor differences in the present results and significant differences in medical costs between Poland, Japan and the UK, the same conclusion holds as regards higher medical costs of endotherapy unless it is extended over a year. Moreover, in the study of Cahen *et al.*, during a long (6-year) observation period, more than half of patients with prolonged endotherapy treatment underwent a drainage procedure; however, the effectiveness of the treatment in this case was much lower. The author explained this as being due to a late operative intervention and an increase in irreversible changes of the pancreas [20].

Critically looking at these studies, especially those evaluating the financial performance, we note that they cannot be easily transferred to Polish conditions. Due to different valuation of the procedures and slightly different methods of calculating direct costs, studies from abroad should be treated only as an indicator of contemporary trends in the treatment of CP. Prior to the use of applications in clinical practice in Poland, further studies are needed in local realities. This work extends so far analyzed direct costs by the analysis of the costs incurred by the National Health Fund and the Social Insurance Institution.

For the payer (NFZ) it is favorable and statistically significantly cheaper to refund the endoscopic procedures in the first year of treatment, but after 2 years of treatment costs of hospital procedures are equalized, to become lower for the surgical group after 3 years of follow-up. However, when considering drug reimbursement, which takes on different principles for both groups, it turns out that from the 3-year perspective there is no statistically significant difference for NFZ, which is refunded by the therapeutic algorithm. For comparison, in the UK the amount associated with the treatment of pancreatic exocrine insufficiency is comparable for both groups, which results from the nature of the specific health care system [19]. Unfortunately, there is a lack of papers comparing that specific problem from the point of view of the health care system.

Besides the epidemiological references according to frequency of incapacity to work, there are no publications evaluating the comparative costs associat-



ed with sickness absence and incapacity for work in both therapeutic algorithms. In that study, no significant differences in terms of social benefits were found, perhaps because of the small number of participants in groups. There are apparent trends that due to the large standard deviations do not reach the threshold of statistical significance. It seems that the number of days off sick and thus the cost for the Social Insurance Institution is lower in the surgically treated group. There is no difference in the amount of paid disability benefits because of the incapacity to work and other social benefits.

## Conclusions

The total medical cost is significantly lower in the surgically treated group in the 3-year follow-up period. In the analysis of the quality of life, pain as the main symptom of CP does not differentiate the two populations studied. Other factors of QoL do not give a clear conclusion, so the parameter determining the ultimate cost-effectiveness ratio is primarily the total medical cost. It follows that in patients in whom the endotherapy extends, exhibits an unsatisfactory efficacy or the chances of success are low, 12 months after the onset of symptoms a multidisciplinary team should be consulted and the surgical treatment option should be considered. In this analysis, we note that both for the health system and social security in Poland with a 3-year follow-up period, there are no statistically significant differences that would prefer one of these methods.

## Conflict of interest

The authors declare no conflict of interest.

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