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Customised Study of Management Strategies in Patients with Chronic Pancreatitis - Single Centre Experience

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Authors' contributions

This work was carried out in collaboration between all authors. Authors TN designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors AS, KS, KSK and TA managed the analyses of the study. Author AT managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Despite advanced developments are available for managing patients with chronic pancreatitis, the disease remains an enigmatic process of uncertain pathogenesis with unpredictable clinical course and management. In the majority of the cases, intractable pain is a major indication for surgical intervention. Other complications related to adjacent organs such as, pancreatic pseudocysts cases, ductal pathology, intractable internal pancreatic fistula or suspected malignancy also require surgery. The surgical drainage approach should address the above problems tailoring to the various therapeutic options to meet individual patient's needs by duodenum-preserving pancreatic head resection in terms of an extended drainage procedure. In this process, the pancreas may be tailored

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to the morphology of the pancreatic gland. The present work is a randomised study done on 110 patients (1995-2010) with alcoholic and tropical chronic pancreatitis. Patients were subjected to both surgical and endoscopic procedures according to the inclusion criteria for both procedures. These results were compared in terms of pain and hospital stay. This study concludes that surgical procedure is far superior to endoscopic drainage for avoiding complications and pain in chronic pancreatitis.

Keywords: Chronic pancreatitis; tropical pancreatitis; ductal hypertension; pseudocysts; pancreatic ascites; chronic pain abdomen; Pancreatico-jejunostomy.

1. INTRODUCTION

Chronic pancreatitis (CP) is a gradually progressive damage to the pancreatic parenchyma which is irreversible and eventually leads to pain, exocrine/endocrine insufficiency with malnutrition. In the majority of patients, pain is the only symptom which makes patients to seek for medical help. The role of intervention comes when there are complications like pseudocysts, biliary or duodenal obstruction and internal or external pancreatic fistulae. Pancreaticoduodenectomy (PD), pylorus-preserving pancreaticoduodenectomy (PPPD), and duodenum-preserving pancreatic head resection (DPPHR) are important treatment options for patients with chronic pancreatitis [1]. Alcohol remains the most common cause of chronic pancreatitis worldwide [2]. The natural history and clinical presentation of chronic pancreatitis vary depending on the form and causal mechanism, although abdominal pain is present in most of the patients [3].

The management strategies of CP involve correct diagnosis and staging of the disease as well as identification of the underlying aetiology. Patients with no definite aetiology, are labelled as idiopathic chronic pancreatitis (ICP), which is further labelled as early and late onset ICP, tropical pancreatitis and small duct chronic pancreatitis. Still there are many cases of acute pancreatitis having underlying chronic pancreatitis, despite different etiopathology. All procedures are equally effective for the management of pain, post-operation morbidity, exocrine insufficiency, and endocrine insufficiency for chronic pancreatitis [1]. In order to guide the clinician: several groups have attempted to design classifications and scorings systems for chronic pancreatitis [4].

Pain severity ranges from severe disabling continuous pain to mild pain attacks and pain-free periods [5]. Careful assessment of phenotyping is essential, including the search for other etiologic risk factors [6].

Prompt recognition and classification with appropriate operative therapy results in low mortality and non-operatively managed pancreatic fistulas [7] Surgical drainage include longitudinal pancreaticojejunostomy [8]. In Surgical correction, complication rate ranges from 6 to 30%, mortality rate from 0 to 2%, and a success rate in achieving long-term pain relief of 65 to 85% [8-15]. Endoscopic correction is done by sphincterotomy, stenting, dilation of strictures, and removal of stones and has a success rate of 30 to 100% [16-23].

For a study performed in India, data were collected from 32 centres for about 1,086 patients. It was found in patients (with an average age of only 39.7 years) that 60% of them had ICP, 38% had alcoholic pancreatitis and 3.8% had classical tropical pancreatitis [24]. In another study from Chandigarh, India; a clinical profile of 155 CP patients in North India identified ICP as most common aetiology including 41.8% of patients with a background of alcoholic history (38.1%), Predominance of males was evident [25].

2. METHODS

Visakhapatnam clinical profile of 110 chronic pancreatitis patients revealed that Alcoholic CP was the most common aetiology observed in 88% followed by Tropical CP in 9.3%, Idiopathic 2.6% and hyperparathyroidism and pancreatic divisum as an etiological factor was observed in 1.3%. Mean age of presentation of patients was 12-30 years.

Here in this study, a randomised trial was done to compare endoscopic and surgical drainage by using parameters which includes outcomes of pain; immediate and late relief, physical and mental health status, morbidity, mortality, duration of hospital stay, number of procedures undergone, changes in pancreatic function and improvement in body mass index. Endoscopic drainage was performed which includes sphincterotomy, dilation of strictures and removal

of stones and this procedure has a success rate of 30 to 70% and recurrence of pain in 38%.

The study was approved by the Medical Ethics committee of the Academic Medical Centre (King George Hospital). Following this, few patients were identified from the Surgical and Medical outpatient clinic of King George hospital (functioning as a tertiary referral centre). These symptomatic patients; who were diagnosed to have chronic pancreatitis (with the exception of patients who had developed pancreatitis following trauma) were given a written consent form to undergo some of the routine evaluations. All symptomatic patients were evaluated by ultrasound, magnetic resonance cholangiopancreatography and contrast-enhanced computer tomography.

Inclusion criteria for surgical approach were: upper abdominal pain refractory to medical treatment (daily pain), inflammatory mass of the pancreatic head ,stenosis of the intrapancreatic common bile duct ,multiple narrowing of the pancreatic main duct ,compression of the portal and/or superior mesenteric vein ,severe stenosis of the peripapillary duodenum ,large persisting pancreatic/peripancreatic pseudocyst after interventional/endoscopic treatment and inflammatory process suspected to be associated with a malignant process.

2.1 Endoscopic Intervention

Endoscopic drainage procedure was performed by endoscopists of the institution in 14 patients. The procedure was performed with the patients under conscious sedation and consent. A stenosis was considered to be present if pancreatogram shows narrowing of the main pancreatic duct, dilatation of the duct by more than 5 mm proximal to the narrowing and incomplete distal runoff of the contrast agent. Overall pain relief was found in 38% of the patients.

If one or more inarticulate stones less than 7 mm in diameter were identified in imaging studies, the patient was referred for endoscopic retrograde cholangio pancreaticography.

2.1.1 Follow-up

If an endoprosthesis had been inserted, an elective endoscopic pancreatogram was scheduled for every 3 months. Persistent strictures were treated by repeated dilation with the sequential insertion of multiple stents [26] and finally subjected for a surgical procedure.

2.2 Surgical Drainage

Surgery was performed within 4 weeks after randomisation by the surgeon in 96 patients. A pancreaticojejunostomy was performed as a drainage procedure by the method of Partington and Rochelle [3]. The Whipple procedure, cystojejunotomy, distal pancreatectomy, cystogastrostomy and cystoduodenostomy have been used for the treatment of patients with pseudocyst and small duct CP. For patients with inflammatory mass, treatment requires a combination of ductal drainage and a limited resection of the pancreatic head by the Beger or the Frey procedure [27,28]. The pancreatic duct was incised over the full length up to 2 cm from the ampulla. When retrieval of concretions from the pancreatic head area required further opening of the duct toward the ampulla, a limited wedge resection of pancreatic tissue was performed. The potency of the anastomosis was evaluated by means of magnetic resonance cholangiopancreatography 3 months after the procedure and again whenever symptoms recurred. Up to 39% of patients who went through lateral pancreaticojejunostomy have evidence of pseudocyst disease at the time of surgery. This can be the source of pain indistinguishable from that of the underlying chronic pancreatitis. Pain relief persists for more than 2 years in only 60% of patients. Twenty-five percent to 66% of patients undergoing pancreatic duct drainage procedures require concomitant biliary or gastric drainage because of the functionally significant obstruction of the bile duct or duodenum. In terms of pain relief, after an observation period of 2 to 20 years, nearly 91.66% of patients were completely pain-free, 6% experienced pain and 2% experienced further episodes of acute pancreatitis.

2.3 Data Collection

Information was obtained during visits at baseline and at predefined intervals of 6 weeks followed by 3, 6, 12, 18, and 24 months after surgery or the first endoscopic procedure. A standardised evaluation of symptoms and laboratory investigations were performed. In addition, quality-of-life scores, as assessed by the Medical Outcomes Study 36-Item Short-Form General Health Survey (SF-36) [29] questionnaire, and the Izbicki pain score were obtained [24]. The latter is a validated pain score, specifically

designed for chronic pancreatitis, that is based on four questions regarding the frequency of pain, intensity of pain (as indicated by a visual analogue score), use of analgesics, and disease-related inability to work; the scale ranges from 0 to 100, with higher scores indicating severe pain. The Dutch Chronic Pancreatitis Registry (CARE) offers a unique opportunity with sufficient power to investigate many clinical questions regarding the natural course, complications, efficacy and timing of the treatment strategies [30].

Data was collected per admission details and per procedures performed. The procedures were classified as diagnostic or therapeutic. Therapeutic interventions encompassed all surgical and endoscopic procedures (including initial interventions), placement of a jejunal feeding tube. The pancreatic endocrine function was evaluated by measuring fasting serum glucose levels and glycated haemoglobin levels and then by collecting data on medication use. The pancreatic exocrine function was assessed by measuring faecal elastase levels.

2.4 Treatment during Follow-up

In patients with persistent or recurrent pain, imaging studies were repeated and evaluated by a multidisciplinary team of gastroenterologists, surgeons, and radiologists. If a recurrent pancreatic-duct obstruction was noticed in patients who had already completed endoscopic treatment and stent therapy was resumed.

2.5 Outcome Measures

The primary outcome measure was pain during the 2-20 year follow-up period, expressed as the average of the Izbicki pain [31] scores obtained at 6 weeks and at 3, 6, 12, 18, and 24 months. The secondary outcome measures were pain relief at the end of follow-up, physical and mental health, morbidity, mortality, duration of hospital stay, number of procedures performed, and changes in exocrine and endocrine pancreatic functions.

Pain relief at the end of follow-up was classified as complete (Izbicki pain [31] score ≤10) or partial (Izbicki pain score >10 after a decrease of >50% pain relief). Treatment was considered to have failed in patients whose treatment was converted from endoscopic drainage to surgery and in those who died because of the treatment. Patients were considered to have endocrine insufficiency if they required treatment (either oral medication or insulin) for glycemic control.

During follow-up, treatment was initiated when the fasting glucose level was above 6.7 mmol per litre (121 mg per deciliter) and the glycated haemoglobin level was more than 6%. Exocrine insufficiency was defined as an elastase level of less than 200 µg per gram of faeces. Changes in pancreatic function (both endocrine and exocrine) were evaluated by dividing the patients into four groups: those who had pancreatic insufficiency at both baseline and follow-up (insufficiency persisted), those who did not have insufficiency at baseline but in whom insufficiency developed during follow-up (insufficiency developed), those who had insufficiency at baseline but not at follow-up (insufficiency resolved), and those who did not have insufficiency at baseline or follow-up (sufficiency persisted) [32].

2.6 Statistical Analysis

Randomisation was performed with blocks of four or six patients by an automated assignment system that concealed the treatment assignments. No stratification was performed. Calculation of the sample size was based on the difference between the average Izbicki pain scores of the two treatment groups during follow-up.

Depending on the distributional properties, outcome measures were expressed as means ±SD or as medians with ranges. The analysis was performed according to the intention-to-treat principle. For each patient, the mean Izbicki pain score and the mean scores on the physical and mental health components of the SF-36 questionnaire were based on the data obtained during follow-up. Missing follow-up data were considered to be missing at random. To adjust for baseline scores, analysis of covariance was performed.

Statistical significance was assessed using Student's t-test for normally distributed continuous data (e.g., age); either the chi-square test for categorical data (e.g., pain relief), with Yates' correction when appropriate (e.g., smoking), or Fisher's exact test for categorical data (e.g., changes in pancreatic function); and the Wilcoxon test for non-normally distributed continuous data (e.g., length of hospital stay). All reported p values were two-sided and were not adjusted for multiple testing.

3. RESULTS

Between 1992 and 2010, a total of 110 patients were screened and underwent randomisation. Overall 14 to 29% complications were observed. The mortality rate was observed to be 0 to 4% (non-surgical), and the success rate in achieving long-term pain relief was observed in 91.6%. The median follow-up time was 24 months for both groups. One patient was lost to follow-up 6 months after undergoing surgery. Alcohol abuse was found in 88%, 66 male patients treated surgically and endoscopically.

3.1 Endoscopic Treatment

Fourteen patients were assigned to endoscopic treatment. Ductal Pancreatic-obstruction was caused by strictures and stones in 11 patients (78.57%), by stones alone in 2 patients (14.28%), and by a stricture alone in 1 patient (7.14%). Out off the 13 patients, complete stone extraction was accomplished in 10 (76.92%).

The stents were in place for a maximum of 27 weeks. Balloon dilation was performed in 11 patients; 9 patients required sequential insertion of more than one stent, and 7 patients had recurrent stenosis during follow-up for which stent therapy and dilatation was performed.

The overall success rate of endoscopic treatment was 38%. The endoscopic treated, three patients were advised surgery because of persistent stenosis; of which two had relief of pain after surgery.

Seven patients who had stent-related complications were treated by replacement of the stent. Stent and dye-related complication like pancreatitis which occurred in four patients and cholecystitis in one; all were treated medically.

3.2 Surgical Treatment

Out of the 96 patients assigned to surgical treatment, 62 underwent a pancreatico jejunostomy. One had to undergo Frey procedure [26] for stone extraction, Distal pancreatectomy was done in 5 patients, Cystogastrostomy in 13 patients, Cysto-jejunostomy in 5 patients, Cystoduodenostomy 2 in patients and one had undergone pancreaticoduodenectomy. Magnetic resonance cholangiopancreatography performed 3 months after surgery and during episodes of pain. But one patient had developed a pancreatic fistula. Overall complications occurred in fourteen patients and 4 patients had mortality. One patient required a repeated laparotomy because of anastomotic leak.

3.3 Outcomes

Overall mean of Izbicki pain score was 59± 21 in the endoscopically managed patients and 27± 19 in the patients who had surgery. Pain relief was achieved at the end of follow-up in 38% of patients who underwent endoscopic intervention and 91.6% of patients who had a surgical intervention ($p=0.007$).

The follow-up score data based on the physical health component of the SF-36 questionnaire were lower in endoscopically treated patients than in surgically treated patients ($p<0.001$). There was no difference in regard to the duration of hospital stay, mental health status but endoscopically treated patients underwent significantly more procedures than surgically treated patients. Hence, the morbidity is more in endoscopically treated patients. Moreover, exocrine function was good in patients who had a surgical correction ($p=0.005$).

4. DISCUSSION

This study shows that in patients with chronic pancreatitis and pancreatic-duct obstruction, surgical drainage was more effective than endoscopic treatment during 20 years of follow-up. The benefits of surgery were demonstrated in terms of pain relief. The surgically treated patients had a better state of physical health. The clinical relevance reflected the difference between having no pain and having pain daily, or between taking no sick leave for pain and being permanently unable to work.

Absolute decompression of pancreatic duct was obtained in patients who were managed surgically. During endoscopic treatment, secondary side branches might be compromised by the presence of a stent but recurrence of strictures and formation of new intraductal stones are common. Endoscopic stenting might even aggravate the formation of strictures, as it has been shown to worsen pancreatic-duct abnormalities [33]. Another advantage of surgery might be the opening of the pancreatic capsule longitudinally during surgical drainage might alleviate interstitial pressure [34]. It has been found that the effects of the endoscopic treatment may occur only after months or even

years of treatment, still many studies have to be made [18,35].

There is another published prospective, randomised trial comparing endoscopic treatment with surgery which showed results similar to the present study and even beneficial signs in surgical treatment (complete pain relief in 37% of patients undergoing surgery vs. 14% of those receiving endoscopic treatment) [36]. There are, a number of retrospective studies have that evaluated endoscopic treatment of pancreatitis [37,38].

In this study, pain score was assessed by a particular scoring system which is particularly designed for chronic pancreatitis. To minimise expectation bias, patients completed the questionnaires in private, and only the study coordinator had access to the clinical report.

The results of the present study cannot be extrapolated to all patients with a ductal obstruction due to chronic pancreatitis. Furthermore, this study had complex pathologic features, with a combination of stricture and stones in most patients. On the basis of the outcome of the study, surgical drainage is the best preferred treatment in patients with chronic pancreatitis. As we see in our recent trends, this operation is being performed laparoscopically, making it even less invasive [39]. It is suggested that more studies should be performed on patients with the less extensive disease, to identify if endoscopic treatment can still be a valuable alternative procedure.

5. CONCLUSION

The study suggests that surgical drainage procedure remains the mainstay for managing complications and pain in chronic pancreatitis.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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