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## An ethical analysis of endoscopic therapy decision-making in patients with refractory substance use disorder and chronic pancreatitis

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### Keywords

Ethics; Gastroenterology; ERCP; Pancreatitis; Addiction

Mr. John is a 55-year-old male with a history of chronic pancreatitis, resulting in chronic abdominal pain and frequent hospitalizations. Over the past 3 years, he has undergone 7 ERCPs with dilation of a main pancreatic duct stricture and stent placement. After ruling out all other possible causes, his treating physician, Dr. Smith, has determined that his pancreatitis is due to his chronic alcohol intake and smoking. Dr. Smith has repeatedly counseled Mr. John about his drinking and smoking and how they are responsible for his chronic pancreatitis. Furthermore, ongoing use will likely lead to progression of his disease. Mr. John promises to quit every time and has on occasion, but relapses shortly after.

Mr. John presents to the outpatient Gastroenterology clinic with his typical complaints of abdominal pain and bloating. Dr. Smith once again determines that the cause of Mr. John's abdominal pain is his chronic pancreatitis. Abdominal imaging suggests recurrence of a pancreatic duct stricture and Dr. Smith believes that an effective treatment might include repeat ERCP. However, Dr. Smith is hesitant to perform the ERCP considering his patient's ongoing alcohol and tobacco use and history of non-adherence.

### 1. Introduction

Chronic pancreatitis (CP) is a disease characterized by pancreatic inflammation with progressive fibrosis of the gland, often leading to loss of both exocrine and endocrine

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Specific author contributions

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Declaration of competing interest

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function. Chronic, debilitating abdominal pain is the hallmark symptom of the disease, marked by frequent disease exacerbations, often leading to emergency room visits and hospitalizations [1–3].

The pathophysiology of CP is complex. Etiologic risk factors associated with chronic pancreatitis can be classified according to the TIGAR-O classification system: 1) Toxic-metabolic, 2) Idiopathic, 3) Genetic, 4) Autoimmune, 5) Recurrent and severe acute pancreatitis, or 6) Obstructive [4]. For the purposes of this article, we will focus on toxic metabolites that are associated with CP, specifically, alcohol and tobacco.

As a result of the chronic process of fibrosis, a stricture or narrowed segment of the main pancreatic duct (MPD) may occur in a subset of patients, leading to duct obstruction. Pancreatic duct stones could also form as a result of the stasis of secretions and calcification of protein plugs, contributing to obstruction [5]. This results in elevated intraductal pressure and may contribute to abdominal pain [1]. In support of this, alleviation of this ductal hypertension leads to at least partial relief of pain in the majority of patients [1,6]. Endoscopic stricture therapy is the preferred initial treatment modality in uncomplicated painful CP with a dilated MPD, given the decreased morbidity compared to surgery [7]. The short-term response rate, defined as a decrease in pain scores, with endoscopic stenting ranges from 67% to 100% [1,8–22], and long-term improvement with pain relief ranges from 37% to 89% [1,9–11,20,21,23–28].

## 2. Background

### 2.1. Epidemiology of CP

The annual incidence rate of CP is estimated to be between 5 and 12/100,000,[29–32] while the prevalence is estimated to be up to 98.7/100,000 persons [33]. The individual suffering associated with CP is considerable, and there are also social, work and financial consequences. For example, the North American Pancreatic Study 2 (NAPS2) demonstrated that both female and male patients with constant pain were more likely to use pain medications regularly, be on disability benefit, have a greater number of days lost per month (work or school) and more near-term and lifetime hospitalizations than female or male patients with intermittent pain [34]. Furthermore, CP results in increased healthcare costs and increased indirect and societal costs. While indirect costs attributable to lost productivity are difficult to quantify, the annual cost of hospitalizations in patients with pancreatitis in the United States has been estimated to exceed two billion dollars [35]. In the same study, 253,753 adult Emergency Department visits were associated with a primary diagnosis of CP [35]. In The UK, a study of the economic burden of CP estimated that chronic pain due to CP alone contributes \$638 million per year [36]. A German study of 265 patients with CP found that 14% took disease-related early retirement and 13% had prolonged unemployment [37].

### 2.2. The role of alcohol and tobacco in CP

There is now an abundance of accumulating evidence on the effects that alcohol and smoking have on the development and progression of CP, with genetic predisposition and

other triggering factors playing a role in the disease. Alcohol is thought to cause up to 80% of CP cases [4,38], particularly in men, though only 5–15% of patients with heavy alcohol use develop pancreatitis, suggesting other factors play a role [4]. In recent years, smoking has emerged as an independent risk factor for CP with detrimental direct effects on the pancreas. Indeed, the NAPS2 study demonstrated the importance of smoking as the primary etiologic factor in women [39]. Ongoing use of alcohol and/or tobacco may be expected to result to progression of fibrosis, increased likelihood of complications of the disease (including diabetes, steatorrhea, osteopathy, pancreas cancer) and more frequent pain flares. Continued smoking and alcohol misuse has been shown to increase the frequency of painful CP relapses [34,40,41]. Patients with CP who stopped drinking had a positive effect on pain and clinical outcome [42–44]. In a long-term clinical outcome study after endotherapy, good clinical outcomes were associated with cessation of smoking [10]. In addition, abstinence has been shown to slow the disease progression and prevent the disease's complications [44,45]. Alcohol abstinence and smoking cessation is recommended for patients with CP [46,47].

### 2.3. Addiction

Addiction is a chronic, relapsing disease of the brain that affects patients who have adverse environmental exposure and are vulnerable due to genetic predisposition [48]. Multiple studies have identified genes associated with vulnerability to addictive behavior, while others have shown an association with substance-specific genes [49]. A study of 1.2 million individuals identified multiple genes involved in alcohol and nicotine consumption [50]. Additionally, social environment has a significant influence on behavior and brain development [48]. In a study examining substance use disorders, 231 probands and 1267 adult first-degree relatives were evaluated, demonstrating an 8-fold increase in risk of drug use disorder among the relatives [51]. In one meta-analysis identifying 12 twin studies and 5 adoption studies, alcohol use disorder was found to be 50% heritable [52]. In a population-based twin study of 1898 participants, nicotine dependence was found to have 72% heritability [53].

Treatment of addictive substance use disorder has met with variable success. In 2008, the US Public Health Service released an update to the guidelines for treating tobacco use and dependence. The update was based on distillation of a literature base of more than 8700 research articles. Of the 45 million smokers in the US, 70% reported wanting to quit, while 44% tried quitting. Unfortunately, unaided success rate was only 4–7% [54]. Even with outpatient treatment and follow up with certified tobacco treatment specialists, the success rate of smoking cessation at 6-months was reported to be 22–25% [55,56]. Unfortunately, smoking cessation is even more challenging in CP patients. When compared to non-CP patients, CP patients had 0% quit rate at 18 months follow up, even when provided free cessation services, and face-to-face individual sessions with a smoking cessation specialist [57]. As for alcohol dependence, in one meta-analysis of 122 randomized clinical trials and 1 cohort study (total of 22,803 participants), the number needed to treat to prevent return to any drinking was 12 and 20 for acamprosate and oral naltrexone, respectively [58]. In an analysis of eight trials involving 3417 participants, no strong evidence was found to

demonstrate the effectiveness of Alcoholics Anonymous or other twelve step facilitation programs for reducing alcohol dependence or drinking problems [59].

Even if addiction therapy were highly efficacious, there is the additional consideration that these therapies are subject to inequality in their accessibility. One study found that quit attempts were similar between insured and uninsured smokers, but long-term uninsured individuals were notably less likely to receive physician advice to quit smoking and use of cessation treatments during quit attempts [60]. In a study of 4756 smokers, it was found that, compared to Caucasian smokers, African American and Hispanic smokers were less likely to receive advice to quit and use cessation treatments [61]. In another study of smokers who were uninsured for more than 6 months who then gained Medicaid coverage, it was found that newly insured patients had a 40% increase in their odds of smoking cessation and nearly triple the odds of having a medication ordered [62]. Homelessness has also been shown to be a negative predictor for receipt of evidence-based treatment of alcohol use disorder, while White race was a positive predictor [63]. The latter finding was consistent with other studies that found significant disparities in services utilization for alcohol use disorder between Whites and other racial/ethnic minorities [64,65].

Clearly, addiction is a complicated mental illness, often with major contributory factors which may be beyond a patient's control. There are limited successful treatment options available, and even if accessible, these are often suboptimal with failure of cessation. Despite these factors, the World Health Organization surveyed 14 countries and found that 12 ranked drug addiction as the first or second most stigmatized health condition out of eighteen [66]. Negative attitude towards patients suffering from addiction are also commonly expressed among healthcare professionals [66,67].

#### **2.4. Role of endoscopic retrograde cholangiopancreatography (ERCP) in the management of CP**

There are several treatment modalities for CP, with initial efforts focused on alleviating the underlying cause of the disease when possible. Exocrine pancreatic insufficiency is managed by pancreatic enzyme replacement therapy. As noted earlier, chronic debilitating abdominal pain is the hallmark symptom of the disease and, for these patients, cross-sectional imaging (i.e. computed tomography, magnetic resonance imaging) is used to differentiate patients into those with "small duct" vs "large duct" disease. Significant obstruction of the MPD is unlikely in patients with small duct disease, leading to therapies focused on symptom control, including analgesics, pain modulators, and inhibition of pancreatic enzyme secretion. On the other hand, those patients with large duct disease, or a dilated MPD, often have obstructive pathology, including a pancreatic duct stricture, stones, or a stenotic pancreatic orifice. Alleviation of this obstruction, either endoscopically (via ERCP) or surgically, would be anticipated to lead to symptomatic improvement [1]. Given the reduced morbidity compared with surgery, ERCP is the first-line option in most situations [7]. In patients with painful CP and a dilated MPD, endoscopic therapy is associated with improved pain scores in the majority of patients, with low adverse event rates [1,8–15]. One study quantified the long term improvement of pain as a change from strong, moderate, or mild at baseline to only weak or no pain, which was achieved in 87% of patients in

the endoscopic treatment arm [9]. Several factors play into increasing the likelihood of successful endoscopic therapy including age, suspected biliary stricture, disease duration, absence or cessation of cigarette smoking and of alcohol intake amongst other factors [68,69]. Details of endoscopic therapy are beyond the scope of this discussion, but typically a few or several ERCPs with pancreatic duct stenting may be required to lead to stricture resolution (and duct clearance of stones, when present), as dilation alone is insufficient. The stricture is the result of the repeated inflammation and fibrosis typical of CP, and aggressive endotherapy with repeated sessions and stent exchanges (with the addition of multiple stents) is often necessary [1,69,70]. Use of plastic stents is the standard of care, with fully covered self-expandable metallic stents used in some settings, but these should still be considered experimental at this time [7,69,70]. Importantly, symptomatic improvement may be seen without complete duct clearance of stones. Furthermore, the duration of the clinical benefit is unpredictable and is not correlated with stent obstruction [7,69,70]. Regardless, scheduled follow up visits with frequent reevaluation and potentially several procedures are necessary, all of which require patients' compliance with adherence to medical recommendations. In patients who continue to drink or smoke, however, pancreatic injury continues to progress, inflammation and fibrosis may continue unchecked, and stricture persistence or recurrence is common [5,41].

An additional point which needs to be considered is the potential for adverse events with ERCP. As with any endoscopic procedure, adverse events related to anesthesia or cardiopulmonary events may occur. Specific to ERCP, adverse events may include infection, bleeding, perforation, and most commonly pancreatitis. The incidence of post-ERCP pancreatitis may range from 3.5% to 10%, but can be as high as 20% in high-risk patients [71,72]. This risk persists despite prophylactic measures taken, including placement of temporary pancreatic duct stents and administration of rectal indomethacin [72–77]. The presence of CP, however, appears to reduce the frequency and severity of post-ERCP pancreatitis, presumably due to the preexisting pancreatic damage/fibrosis [74,78].

With this background, in this manuscript we intend to address the question: What are the ethical obligations and limitations of the treating physician in providing or withholding non-emergent endoscopic therapy when patients with alcohol- or tobacco-related CP continue to drink or smoke despite medical advice to quit?

### 3. Ethical analysis

CP is frequently encountered in GI outpatient clinics. Gastroenterologists are often faced with the decision of whether to provide or withhold endoscopic therapy for patients affected by this chronic condition. This hesitancy to continue to provide repeated therapy via ERCP may arise due to the perceived misalignment between the patient's behavior and their own best interest. In such cases, gastroenterologists are faced with an ethical tension in deciding whether, and to what extent, they should continue to provide this treatment given what appear to be voluntary, poor choices on the part of patients—that their willful choices are, in this sense, a primary *cause* of their own disease. In this way, we implicitly assign them responsibility for their illness in ways that we do not for many other chronic illnesses. Gastroenterologists encounter this dilemma while having a profound sense of duty and

fidelity to their patients and to their patients' well-being and best interest. The case of Mr. John exemplifies this scenario and he is representative of the millions of people who suffer from addiction and its consequences. The weight assigned to Mr. John's apparent willful choices to continue to use harmful substances is heavily influenced by the perception of personal responsibility that affects his decisions. Addiction is a disease process that is profoundly shaped by genetic predisposition and environmental influences. Moreover, although volition and behavioral issues clearly play a causative role, the historical blame that society and the medical profession have placed on patients suffering from addiction is not proportional to the role played by comparable volitional factors. Additionally, the treatment options for patients suffering from addiction - even if available - are suboptimal, not always widely available and accessible, and are associated with variable success rates and relatively poor efficacy outcomes. With these issues in mind, Mr. John's inability to quit becomes more understandable, merits less personal blame and responsibility, and helps to put his share of personal responsibility in a larger perspective.

### 3.1. Decision-making capacity

Mr. John was assessed to have full capacity, and the relationship between alcohol/tobacco and his CP had been made clear to him on multiple occasions. He demonstrates 1) an understanding of the disease process and how his addiction is leading to inflammation and fibrosis of his pancreas resulting in CP and pain; 2) the ability to reason and weigh different treatment options; 3) the ability to verbalize his preferences in regard to the treatment plan; 4) the ability to provide consent. Having capacity entails making choices and decisions that govern one's own health, even if those decisions are perceived by the medical team as being misaligned with one's best interests. Autonomous choices must be respected even in situations where physicians disagree with the choices made. Honoring patients' choices that misalign with their best interests often results in emotional distress for the treating physician, and may hinder or adversely affect the patient-physician relationship. Nonetheless, even with this perceived misalignment, providers have an obligation to provide all the details relating to patients' diseases and disease processes. In a survey of CP patients, only 39% of patients reported that their provider has specifically mentioned the effect of smoking on the pancreas [79]. The understanding and insight that may be gained by framing Mr. John's behaviors through the lens of addiction may be beneficial in mitigating the blame we sometimes assign to patients. Understanding addiction as a complicated brain disease with multiple non-volitional contributors is helpful to understanding Mr. John's case and the role his behavioral pathology plays in his pancreatic pathology. What is more, because of the deficiencies and inefficiencies surrounding the availability and effectiveness of addiction treatment, the perceived gap diminishes between the responsibility we might assign to Mr. John's visible life choices and his best interests.

### 3.2. Patients' best interests vs. autonomy

Physicians' recommendations in the best interest of their patients sometimes conflicts with patients' rights to make autonomous choices about their own health and treatment. In the specific setting of endoscopic therapy for CP, because gastroenterologists are the "gatekeepers" of the procedure, there may be a further tension arising out of the physician's sense of conflicting obligations to the patient's good and to the patient's autonomy, but also

to a sense of responsibility for stewarding the resources needed to perform ERCP (personnel time, materials, procedure room time, etc.). This raises issues regarding distributive justice, “the fair distribution of the burdens and benefits of social cooperation among diverse persons with competing needs and claims” [80], and the appropriateness of performing repeated interventions. Adding to that complexity is the fact that providing ERCP to Mr. John this one time will probably not achieve the end goal of complete resolution of the disease process and underlying cause, as additional endoscopic therapies will likely be required. Moreover, these additional procedures put him at risk for adverse events associated with ERCP. With a risk of unsuccessful intervention with repeated ERCP, unfavorable outcomes with continual substance abuse, and the risk of adverse events, the treating endoscopist might find him or herself in a highly distressing situation, where the decision not to provide ERCP is the most appropriate one. Nonetheless, in the event the treating gastroenterologist elects to withhold ERCP due to the aforementioned considerations, the patients are within their rights to seek another physician who may be willing to provide the procedure. The physician’s frustration with the situation also plays a role in the relationship with the patient. In a survey of 1076 physicians from 40 different specialties, one of the most reported communication problems causing physician frustration in communicating with patients is lack of adherence. Participants in the survey specifically reported issues such as, “The patient didn’t follow my instructions.” and “The patient did not accept responsibility for his/her own health care [81]”. In another study regarding moral problems faced by nurses working in dialysis, patient non-adherence ranked second amongst the most frequent issues causing moral distress for the medical team [82].

#### 4. Practical approaches

A multidisciplinary team approach leads to improved outcomes in numerous different complex medical circumstances, including acute and chronic pancreatitis [83–87]. For example, when a subspecialized abdominal staff radiologist reread imaging studies during a multidisciplinary pancreas conference, changes in the management occurred in 38.5% of cases [88]. The decision on how to proceed in Mr. John’s case is complex as depicted here, but a multidisciplinary approach might have more favorable outcomes to all parties involved. A multidisciplinary team focused on acute/chronic pancreatitis might consist of “core” and “allied” members that could include but is not limited to gastroenterologists, pancreatologist, advanced endoscopist, surgeons, radiologists, radiation oncologist, oncologist, pathologists, primary treating physicians, a chairperson, and a coordinator, depending on the clinical case [86]. The team would ideally include “support members” that could include nutritionists, pharmacists, and social workers. The team and total number of specialists could vary depending on available specialists and the size of the medical center. In the case of Mr. John, the inclusion of an addiction specialist who could assess Mr. John’s willingness to quit and guide him through available options, as well as a pain management specialist who could evaluate Mr. John’s pain and explore possible venues for pain management, would potentially be beneficial in a multimodal approach to his complex disease. The addition of a therapist could also be beneficial as cognitive-behavioral therapy has shown promising results in reducing pain intensity and pain interference from baseline in patients with CP [89]. From a societal level, a remote-based central multidisciplinary team could

also be implemented to assess complicated cases, weigh in on different options from experts' standpoints, and facilitate transfer to tertiary referral centers as needed. In the UK, a multidisciplinary hub-and-spoke model has been implemented for the management of severe acute pancreatitis [90]. In the Netherlands, the Dutch Pancreatitis Study Group introduced a 24/7, online, nationwide, multidisciplinary expert panel for clinicians treating acute necrotizing pancreatitis [91]. The complexity of the problem of co-existing substance use disorder that contributes to causing and perpetuating CP in this patient population eludes facile solutions. It may be for this reason that GI Societies and groups that issue guidelines have avoided inclusion of simplistic responses and recommendations to treating clinicians. However, such societies are in a position both to advocate for increased resources and access around the treatment of tobacco and alcohol use and to support more forcefully legislative solutions that lead to decreased use of harmful substances (such as increased taxation). Such efforts could take shape by increasing discussions on a wider, global scale to draw more attention to the complexity and prevalence of the problem at national and international meetings. Supporting the physician's rights to make treatment decisions without abandoning patients might also be within the purview of consensus statements and/or expert recommendations in this domain.

## 5. Summary

What are the limits of ethical obligations faced by treating gastroenterologists when patients continue harmful and addictive substances? The patient may be congratulated when he or she successfully stops his alcohol use after repeated failed attempts. What if he perseveres with smoking, continuing a habit which will likely impede the desired outcome of endoscopic therapy, should the physician withhold this procedure? Under what circumstances would it ever be ethical to withhold an elective ERCP and possible treatment?

Mr. John's case of CP, which is both caused and perpetuated by substance abuse, presents a common but complex and sometimes frustrating clinical ethical quandary for treating gastroenterologists. Endoscopic therapy, typically performed by highly-trained specialists, is an intervention which may be considered in a subgroup of patients. In Mr. John's case, this therapy may provide symptomatic relief. However, this neither cures the disease nor treats the underlying cause, which includes ongoing use of harmful substances. Furthermore, clinical benefit following endoscopic intervention is likely to be of limited duration in this situation. It is helpful to see the set of clinical ethical choices embedded in such treatment decisions from two viewpoints. On one hand, treating physicians could perform ERCP and provide endotherapy whenever needed and requested, without specific limitations. This position derives from unfettered and blind deference to patients' autonomy. At the other extreme, physicians could use the power inherent in their gatekeeper function to set specific limits (e.g. no more ERCs after X number of procedures; no further ERCs if there is ongoing substance use). An example of a similar limitation would be the Swiss Guidelines for Diagnosis and Management of Chronic Obstructive Pulmonary Disease, which state that "smoking cessation is a requirement for long-term oxygen therapy [92]." This position primarily derives from considerations of distributive justice and the ethical distribution of resources, which in the case of ERCP, has been shown in multiple studies to have significant mismatch between availability of the procedure and demand [93,94]. Requiring abstinence

and a change in behavior in direct exchange for providing a procedure would not be appropriate, however, since our current understanding of these addictions is that they are not primarily willful behaviors. The same discussion can be held when deciding whether to consider surgical intervention in CP patients who continue their substance abuse. In patients with benign disease who do not respond or may not be considered for endoscopic therapy (e.g. those with an excessive stone burden throughout the gland), surgical referral is often pursued. However, surgeons may struggle with the same ethical question, specifically whether to proceed with a procedure which may not lead to long term remission due to relapse of substance use. Similar ethical considerations might be applied, and careful ethical analysis would be pertinent in parallel ways. While the risk-benefit ratio of surgery is different, and likely less favorable, similar constructs for navigating through this ethical dilemma could be beneficial. As is frequently the case in complex clinical ethical issues, it is the physician's responsibility to find balance in how treatment decisions order and respect the various values which come into tension in such situations. Such balance is what the authors aim for in this scenario. Through evaluating each case on a case-by-case basis, continuing to advocate for addiction treatment, facilitating access to different addiction therapies, and performing a conscientious risk-benefit analysis factoring in the availability of ERCP, expected benefits for the patient, potential adverse events, and other patients waiting to receive the same intervention whom the procedure might offer a more favorable risk-benefit ratio. We have tried to present the inherent ethical issues in this patient's case in ways that illuminate the primary ethical complexities. For example, clinicians are subject to popular and pervasive misconceptions about the degree to which substance use disorders (and their downstream effects on health) derive from willful choices. We have also tried to highlight the fact that effective opportunities and therapies for addiction are inadequate, leaving patients with few options to heal their underlying disorder. We believe that gastroenterologists who perform ERCP and treat patients with chronic pancreatitis are driven by their desire to serve their patients' best interests and to respect their autonomy at the same time. Finding a wise balance in performing repeated endoscopic procedures, fiercely advocating for patients' best interest, identifying resources and providing encouragement of substance cessation, while at the same time affording understanding of the complex origins of this disease will remain a challenge for all gastroenterologists involved in the treatment of this patient population.

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