FINAL STATEMENT

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NATIONAL INSTITUTES OF HEALTH

STATE-OF-THE-SCIENCE CONFERENCE STATEMENT

Endoscopic Retrograde Cholangiopancreatography (ERCP) for Diagnosis and Therapy

January 14-16, 2002

NIH Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.

The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research."

Introduction

Diseases of the hepatobiliary system and pancreas are frequently encountered in clinical practice. An examination of the bile ducts or pancreatic ducts is often required for the appropriate diagnosis and management of patients with pancreatic or hepatobiliary diseases. These conditions include gallstones and their complications, pancreatic and biliary cancers, pancreatitis and its complications, and pancreaticobiliary pain. Over the last three decades, the dramatic technical advances of flexible endoscopy have resulted in endoscopic retrograde cholangiopancreatography (ERCP) being used as a primary method of diagnosing and treating many pancreatic and biliary diseases.

ERCP provides visualization of the ampulla of Vater (point of entry of the bile and pancreatic ducts) and, when combined with radiography, provides high-quality visualization of the bile ducts and pancreatic ducts. ERCP allows tissue or cells to be acquired for diagnosis using brush cytology and biopsy and has been utilized for the removal of bile and pancreatic duct stones, the treatment of biliary strictures, and the palliation of malignancy. ERCP is a gastrointestinal endoscopic procedure requiring conscious sedation, which is performed by gastroenterologists or other physicians with special training. The procedure carries a risk of acute pancreatitis.

hemorrhage, perforation, and, rarely, death.

ERCP first came into use about 30 years ago and has been applied to the diagnosis and management of a variety of hepatobiliary and pancreatic disorders. Since then the role of ERCP relative to other means for diagnosing and treating these diseases has evolved. Over the last two decades, several new diagnostic modalities have been developed, including ultrasound (transabdominal and endoscopic), computed tomography (CT) (single and multislice helical), magnetic resonance imaging (MRI), magnetic resonance cholangiopancreatography (MRCP), and intraoperative cholangiography. These techniques have proven useful in the diagnosis and staging of pancreatic and hepatobiliary diseases and may obviate the need for ERCP in some cases. An important function of this conference is to explore the optimal and appropriate usage of ERCP relative to these new technologies utilizing an evidence-based review of the clinical literature.

> This National Institutes of Health (NIH) State-of-the-Science Conference on Endoscopic Retrograde Cholangiopancreatography (ERCP) for Diagnosis and Therapy was convened on January 14&endash;16, 2002, to examine the current state of knowledge regarding the use of ERCP in clinical practice and to identify directions for future research. Specifically, the conference explored the following key questions:

1. What is the role of ERCP in gallstone disease?
2. What is the role of ERCP in pancreatic and biliary malignancy?
3. What is the role of ERCP in pancreatitis?
4. What is the role of ERCP in abdominal pain of possible pancreatic or biliary origin?
5. What are the factors determining adverse events or success?
6. What future research directions are needed?

During the first day-and-a-half of the conference, experts presented the latest ERCP research findings to an independent, non-Federal panel. The panel was composed of practicing clinicians, biomedical scientists, clinical study methodologists, and a public representative. After weighing all of the scientific evidence, the panel drafted a statement addressing the key questions listed above. The panel's draft statement was presented to the conference audience on the final day of the conference.

The lead sponsors for this conference were the National Institute of Diabetes and Digestive and Kidney Diseases and the NIH Office of Medical Applications of Research. Cosponsors included the National Cancer Institute and the U.S. Food and Drug Administration.

The Agency for Healthcare Research and Quality (AHRQ) prepared the systematic review of the medical literature on ERCP through a contract with the BlueCross BlueShield Technology Evaluation Center Evidence-based Practice Center.

1. What is the role of ERCP in gallstone disease?

The medical and financial burden of gallstone disease in the United States is high. It is estimated that 20 million Americans harbor gallstones. The magnitude of this problem is underscored by the estimated 700,000 cholecystectomies performed annually in the United States. Two-thirds of individuals with cholelithiasis are asymptomatic. Of these, 2 to 4 percent per year will develop symptoms. For those with symptoms, approximately 40 percent per year will experience recurrent symptoms throughout their lifetimes. In contrast to cholelithiasis, the natural history of choledocholithiasis is not well characterized.

Individuals with asymptomatic cholelithiasis need no treatment, and for these individuals there is no role for ERCP. Common bile duct stones are frequent sequelae of cholelithiasis. Several options for the diagnosis of common bile duct stones include ERCP, MRCP, endoscopic ultrasound (EUS), and computed tomographic cholangiography (CTC). Although ERCP is invasive, it is the only one of these options that can also be used to treat common bile duct stones.

ERCP is very sensitive in detecting common bile duct stones, although occasionally small stones may be missed. Both MRCP and EUS have been evaluated for the detection of common bile duct stones using ERCP as the reference standard. The sensitivity and specificity of these techniques exceed 90 percent when compared with ERCP. CTC and abdominal ultrasound are both less sensitive than ERCP in detecting common bile duct stones. Improvements in MRCP technology are occurring rapidly; however, the latest advances are not uniformly available nationwide. EUS is less widely available than MRCP and requires endoscopy.

The probability that a patient has a common bile duct stone is a key factor in determining diagnostic and treatment strategies. Risk factors for common bile duct stones include jaundice, abnormal liver chemistries, and abdominal ultrasound evidence of ductal dilatation. The absence of all of these risk factors is a strong indicator for the absence of common bile duct stones.

The presence of common bile duct stones must be considered in all patients

undergoing laparoscopic cholecystectomy for cholelithiasis. Common bile duct stones can be removed by preoperative ERCP, laparoscopic common bile duct exploration, or postoperative ERCP. There is no role for preoperative ERCP in patients with low probability of choledocholithiasis because of the low yield. For patients with suspected choledocholithiasis, an operative cholangiogram at the time of laparoscopic cholecystectomy should be performed to definitively demonstrate the presence or absence of common bile duct stones. In patients with choledocholithiasis, laparoscopic common bile duct exploration and postoperative ERCP are comparable in achieving stone clearance and in safety. Postoperative ERCP appears to be associated with greater health care resource use, increased length of stay, and higher cost. Accordingly, laparoscopic common bile duct exploration is more efficient and is preferable when surgical proficiency in this technique is available. Otherwise, postoperative ERCP is indicated for patients with retained stones. Decisions regarding individual patients will depend on local expertise. In selected patients at prohibitive operative risk, ERCP with stone clearance alone may be definitive therapy.

For patients with suspected biliary pain who have had prior cholecystectomy and have a low probability of common bile duct stones, diagnostic modalities less invasive than ERCP (i.e., MRCP or EUS) are preferred. In the clinical setting in which the probability of a common bile duct stone is not low, ERCP and, when indicated, sphincterotomy with stone removal, is the preferred initial approach. ERCP with sphincterotomy is also the primary treatment for patients with cholangitis secondary to common bile duct stones. These patients require immediate resuscitation with intravenous fluids and antibiotics. For those patients who do not improve promptly, ERCP with sphincterotomy and duct drainage is indicated as soon as possible. In contrast, for those patients who improve, urgent (within 24 hours) ERCP and sphincterotomy are indicated.

Microlithiasis (i.e., biliary sludge) may be important in causing pancreaticobiliary symptoms. For patients with suspected common bile duct stones who have a normal ERCP, there may be a role for bile analysis to detect crystals.

2. What is the role of ERCP in pancreatic and biliary malignancy?

Approximately 30,000 new cases of pancreatic cancer and 7,000 biliary tract cancers are diagnosed annually in the United States. Few of these patients will survive 5 years, and most will succumb in less than 2 years. CT scanning is the principal means for initial diagnosis and staging of these

neoplasms. The detection and staging of pancreatic and biliary tract cancers are best accomplished with contrast-enhanced CT scanning, MRCP, or EUS, but not ERCP. These modalities are relatively new and are based on technology that will continue to evolve, but it is clear that state-of-the-art, less invasive imaging is preferable to ERCP for diagnosis and staging in the overwhelming majority of cases.

ERCP is used for diagnosis and palliation in patients known or suspected to have pancreatic or biliary malignancies. However, there is very sparse information on the frequency with which ERCP is used for specific cancer types and stages or its influence on clinical management and outcomes. ERCP may be very beneficial in some cases and much less so in others. The selection of patients and timing in the course of disease where ERCP is used are critically important in maximizing the benefits.

ERCP is unnecessary for the diagnosis of cancer in a patient presenting with a localized pancreatic mass initially seen on a CT scan, if the patient is a candidate for surgery. Preoperative stenting and staging by ERCP in such cases confers no measurable advantage and is not supported by evidence from clinical trials. Preoperative ERCP may complicate or preclude surgical intervention. Contrast-enhanced CT or MRI scanning performed with a pancreaticobiliary protocol is usually sufficient for staging prior to surgical intervention. Preoperative CT angiography (CTA), MR angiography (MRA) and/or MRCP or EUS may be used if indicated.

Unfortunately, most cases of pancreatic cancer are not detected at a curable stage, so only palliation may be offered. Tissue diagnosis is required before chemotherapy and/or radiation therapy. EUS, percutaneous CT- or ultrasound-guided biopsy, and ERCP can provide the necessary tissue. ERCP tissue diagnosis may be achieved using needle aspiration, brush cytology, and forceps biopsy. Individually the diagnostic yield from these techniques is low, but their combination somewhat improves the ability to establish a tissue diagnosis. ERCP is not always successful in making a diagnosis by tissue sampling but offers the potential advantage of biliary tract decompression with a metal or plastic stent placement.

ERCP is the best available means for direct visualization to diagnose and biopsy ampullary malignancies. ERCP is useful for palliation in patients with biliary tract cancers. The role of ERCP in cholangiocarcinoma is parallel to that for pancreatic cancer. However, it may be useful for the diagnosis of biliary tract cancers, for example, in patients with underlying sclerosing cholangitis. In addition, it may be helpful in determining the extent of the cancer.

Palliative intervention for obstructive jaundice in pancreatic and biliary cancer may involve ERCP with stenting or surgery. The available evidence

does not indicate a major advantage to either alternative, so the choice may be made depending on clinical availability and patient or practitioner preference. The technical skills to perform ERCP are widely available, and this modality may be preferable to surgery in some cases due to lower overall resource utilization and shorter hospitalization. If ERCP and stenting are used, metal stents remain patent longer than plastic. Metal stents may be preferred in patients who are expected to survive longer than 6 months.

3. What is the role of ERCP in pancreatitis?

ERCP has been used for both the diagnosis and treatment of pancreatitis, a condition that may be encountered in three distinct clinical scenarios: acute pancreatitis, recurrent pancreatitis, and chronic pancreatitis.

Acute Pancreatitis

The majority of patients with acute pancreatitis develop interstitial pancreatitis, which has a very low mortality. The remainder develop pancreatic necrosis, with a mortality of 10 to 20 percent. There are numerous causes of acute pancreatitis, alcohol and gallstones being the most common. In patients who present with the typical findings of acute pancreatitis (elevated pancreatic enzymes, abdominal pain), ERCP has no role except when the diagnosis of acute biliary pancreatitis with concomitant cholangitis is suspected. Fever and/or abnormal liver chemistries suggest these diagnoses. Noninvasive imaging studies are the preferred diagnostic modalities, because these tests can define the pancreatic anatomy and the extent of the disease, can diagnose and quantify necrosis, and can determine whether pseudocysts are present. The role of MRI/MRCP is increasing but has not yet been fully defined.

In patients with severe biliary pancreatitis, trials comparing early ERCP versus delayed ERCP show a benefit of early intervention. This is the only clinical situation in which the evidence supports intervention with ERCP for acute pancreatitis.

In patients with acute pancreatitis with necrosis, some authors have noted a high incidence of ductal disruption, which may be suspected on the basis of high amylase/volume ascites. In such cases, ERCP with pancreatic stent placement has been utilized, although the evidence to support such an approach is weak. A randomized controlled trial evaluating endoscopic intervention with ERCP could provide useful information.

Recurrent Pancreatitis

When the etiology of recurrent pancreatitis has not been defined by history (e.g., drugs, alcohol, family history), laboratory tests (e.g., calcium, triglycerides), and adequate pancreaticobiliary imaging (e.g., abdominal ultrasonography, CT), further evaluation may be considered. Potential causes include biliary stones, microlithiasis, pancreas divisum, small neoplasms, or sphincter of Oddi dysfunction (SOD). Various anatomic abnormalities can also cause recurrent pancreatitis. MRCP or EUS should be undertaken. If the imaging study is negative, then ERCP with sphincter of Oddi manometry (SOM) can be considered. ERCP without concomitant SOM has no role, with the possible exception of when pancreas divisum is being considered. If the imaging study defines the cause of the recurrent pancreatitis, then appropriate treatment should be undertaken.

When recurrent pancreatitis is attributed to pancreas divisum, studies have suggested that ERCP treatment with stent or sphincterotomy decreases recurrent episodes of pancreatitis and reduces pain. Similarly, a single trial provides evidence that ERCP plus stenting reduces episodes of acute recurrent pancreatitis, but further research is warranted.

Chronic Pancreatitis

For the patient who presents with chronic abdominal pain or the possibility of pancreatic insufficiency (e.g., diabetes, malabsorption), the diagnosis of chronic pancreatitis should be considered. ERCP, MRI/MRCP, EUS, and CT have high degrees of accuracy for diagnosing structural abnormalities. There may be little correlation between the severity of symptoms and the abnormalities seen on the study.

ERCP drainage of pancreatic pseudocysts has been employed, and the results of several studies suggest that ERCP provides a similar rate of pain relief as surgery, with equivalent or reduced mortality. These studies also suggest that regression of pseudocysts occurs in the majority of patients following ERCP drainage. Formal randomized comparisons of ERCP drainage with surgery and interventional radiology are warranted.

Reports of treatment of chronic pancreatitis with ERCP by removal/destruction of stones, placement of stents, and dilation of strictures suggest that both immediate and long-term pain relief are possible. No controlled studies support the generalizability of this finding or the merit of this approach compared to other management strategies. Studies in this area would be of value.

4. What is the role of ERCP in abdominal pain of possible pancreatic or biliary origin?

The recommendations concerning this topic were the most difficult to derive. The validity of sphincter of Oddi dysfunction (SOD), especially types II and III, as a diagnostic entity has been questioned largely because, in contrast to the other topics, SOD lacks concrete pathological findings.

The differential diagnosis of abdominal pain of possible pancreatic or biliary origin is vast and includes clinically apparent entities such as biliary obstruction from stones and strictures (malignant and benign), cholecystitis, pancreatitis, and malignancy, as well as functional disorders, such as irritable bowel syndrome and, most notably, SOD.

SOD refers to an abnormality in sphincter of Oddi contractility. This benign, noncalculous, obstructive disorder may be responsible for recurrent abdominal pain of a biliary or pancreatic pattern for which an anatomic or structural lesion cannot be found. One classification system proposed for this elusive diagnosis follows. Type I biliary SOD includes all of the following: typical biliary-type pain (lasting 30 minutes and occurring at least once a year), elevated alanine transaminase and aspartate transaminase on two occasions, dilated common bile duct (>12 mm) or delayed biliary drainage (>45 min). Type II biliary SOD requires biliary-type pain and at least one additional criterion, while type III SOD is defined by pain alone and may represent part of the spectrum of functional abdominal pain.

The definition of pancreatic-type SOD is similar to that outlined for the biliary type. Type I includes recurrent pancreatitis or pain suspected to be of pancreatic origin, elevated amylase and/or lipase, a dilated pancreatic duct, and delayed emptying of the pancreatic duct; type II requires the presence of presumed pancreatic pain plus at least one additional factor defining type I; type III is defined by pain alone.

The management of SOD has been dependent upon the classification type. Management of patients with type I SOD is the most straightforward. Patients with type I should have an initial noninvasive imaging study, such as abdominal ultrasound, CT, MRCP, or EUS to exclude the presence of structural lesions. In patients with biliary-type SOD and an intact gallbladder, cholecystectomy should be considered as the initial therapeutic modality. In the postcholecystectomy patient, endoscopic, biliary sphincterotomy is effective for the relief of symptoms. The management of type I pancreatic SOD requires dual (biliary and pancreatic) endoscopic

sphincterotomy (ES).

The pathophysiology and natural history of types II and III biliary or pancreatic SOD are controversial. Data regarding pancreatic SOD are sparse, making the management of this disorder even more controversial than its biliary counterpart. The initial evaluation includes the performance of an imaging study of the pancreaticobiliary region (ultrasound, CT, EUS, or MRCP) to exclude structural lesions. It has been suggested that gallbladder dysfunction should also be excluded by biliary scintigraphy and possible cholecystectomy. To guide management of type II SOD, sphincter of Oddi manometry (SOM) of both the biliary and pancreatic sphincters has been recommended. Elevation of sphincter of Oddi pressure, defined as >40 mmHg, is the best predictor of outcome in response to ES in this subset of patients (up to 90 percent clinical benefit after 4 years). In the case of pancreatic SOD, dual ES is recommended. These complex examinations and therapeutic procedures should be executed ONLY by endoscopists possessing expertise in this particular area because of the extremely high rate of severe complications in this young, otherwise healthy group of individuals. The placement of pancreatic stents in association with these procedures has been recommended in order to reduce the rate of such complications, in particular, severe pancreatitis.

The diagnosis and management of type III SOD are most difficult. Invasive procedures should be delayed or avoided if possible. Trials of anticholinergics, antidepressants, nonspecific pain relievers, and/or calcium-channel blockers should precede invasive approaches. The effectiveness of these agents is yet to be defined. Diagnostic ERCP has NO ROLE in the assessment of these patients. It is precisely the typical SOD patient profile (young, healthy female) that is at highest risk for ERCP-induced severe pancreatitis and even death. Indeed, the risk of complications exceeds potential benefit in many cases. Therefore, ERCP, if performed, must be coupled with diagnostic SOM, possible dual sphincterotomy, and possible pancreatic stent placement. ERCP with SOM and ES should ideally be performed at specific referral centers and in randomized controlled trials that examine the impact and timing of therapeutic maneuvers on clinical outcome.

5. What are the factors determining adverse events or success?

The main complication of ERCP is pancreatitis. Other complications include hemorrhage, perforation, cholangitis, cholecystitis, stent-related complications, and cardiopulmonary complications. Pancreatitis occurs in

about 5 to 7 percent of patients undergoing ERCP, whether for diagnosis or therapy. Complications vary for different indications for ERCP. There is a need for a more standardized description of adverse events for ERCP.

More data are needed about the frequency and possible causes of adverse events. Available data show that adverse events appear to be related to features of the patient, the procedure, the endoscopist, and the institutions. To further complicate matters, different adverse outcomes may be predicted by different sets of risk factors.

Because patient-related factors are important determinants of risk, prudent patient selection has a major role in reducing complications of ERCP. The highest rate of pancreatitis (on the order of 20 percent and regardless of whether SOM is done) occurs in young healthy females with normal bilirubin who are suspected of having SOD. Further, about one-fifth of these cases of pancreatitis is severe. Overall it is important to recognize that the highest rate of complications may occur in the group of patients that least needs ERCP, and so the avoidance of unnecessary ERCP is the single best strategy to avoid post-ERCP pancreatitis.

Features of the procedure itself predict pancreatitis, including difficult cannulation, pancreatic injection, and use of precut sphincterotomy. It is unclear whether SOM independently increases risk of pancreatitis. Risk for pancreatitis is not related to comorbidity or whether the procedure is for therapy or diagnosis. For persons receiving ES for SOD, severe pancreatitis may be reduced by pancreatic stenting. Currently, however, most endoscopists have little experience with this technique, and a failed attempt to place a stent may be worse than no procedure at all. More research is needed to assess the role of pancreatic stenting in preventing post-ERCP pancreatitis. Research is also needed to assess different electrocautery approaches and pharmacologic approaches to prevent post-ERCP pancreatitis.

The rate of post-ES hemorrhage, about 0.2 to 5 percent, is related to anticoagulation (within 3 days after endoscopic sphincterotomy), coagulopathy, and acute cholangitis.

Cardiopulmonary complications, while uncommonly related to ERCP, are the leading cause of death from ERCP and occur in older, sicker patients. Such complications might be lessened by close attention to choice of patients, to sedation and analgesia, and to appropriate collaboration with anesthesiologists to manage high-risk or difficult-to-sedate patients. Cholangitis is a complication of failed or incomplete biliary drainage.

Although few data are available to assess operator skills in performing ERCP, competence in consistently performing deep common bile duct

cannulation may not routinely be achieved until the performance of at least 200 ERCPs. Further research would be useful to assess skill and to help set target numbers for training. A volume of one or more endoscopic sphincterotomies per week may be important in keeping complication rates low. Last, a center's ERCP case volume may also be related to rates of complications and failed cannulations. Having a specialized team that includes radiologists, nurses, and endoscopic technicians may have favorable impact on outcomes. When the number of procedures is used as an indicator of skill, it must be recognized that this is a proxy for the skills and outcomes that one is trying to measure, and there may be better ways to conduct measurements. If the numbers of ERCPs needed to achieve and maintain optimal competence are greater than generally occur in training or practice, it may be prudent to concentrate more advanced ERCPs in appropriate centers. Simulator technology, when further developed, may provide an important method for acquiring or maintaining skills.

6. What future research directions are needed?

There is a critical and immediate need to improve the quality of clinical trials for the study of pancreaticobiliary diseases. The need can be met by initiating a cooperative group mechanism with the development of infrastructure for the multicenter participation in the design of prospective, randomized phase III clinical trials of high quality. This is the most important research objective for the future development of ERCP in clinical practice. Future research is recommended in the following areas:

- ERCP removal/destruction of pancreatic stones, placement of stents, and dilation of strictures versus surgical management in patients with chronic pancreatitis and pain
- ERCP with stent placement versus alternative therapies in patients having acute pancreatitis with necrosis
- The pathogenesis, natural history, and management of patients with presumed SOD, recurrent pancreatitis, or pancreas divisum
- The clinical significance, natural history, and management of microlithiasis or "biliary sludge"
- There is a need to enhance and evaluate training for laparoscopic common bile duct exploration (and other surgical techniques) and to improve training for advanced endoscopy. The use of simulators and other new technologies should be studied.

Conclusions

- In the diagnosis of choledocholithiasis, magnetic resonance cholangiopancreatography (MRCP), endoscopic ultrasound (EUS), and ERCP have comparable sensitivity and specificity.
- Patients undergoing cholecystectomy do not require ERCP preoperatively if there is low probability of having choledocholithiasis.
- Laparoscopic common bile duct exploration and postoperative ERCP are both safe and reliable in clearing common bile duct stones.
- ERCP with endoscopic sphincterotomy (ES) and stone removal is a valuable therapeutic modality in choledocholithiasis with jaundice, dilated common bile duct, acute pancreatitis, or cholangitis.
- In patients with pancreatic or biliary cancer, the principal advantage of ERCP is palliation of biliary obstruction when surgery is not elected.
- In patients who have pancreatic or biliary cancer and who are surgical candidates, there is no established role for preoperative biliary drainage by ERCP.
- Tissue sampling for patients with pancreatic or biliary cancer not undergoing surgery may be achieved by ERCP, but this is not always diagnostic.
- ERCP is the best means to diagnose ampullary cancers.
- ERCP has no role in the diagnosis of acute pancreatitis except when biliary pancreatitis is suspected. In patients with severe biliary pancreatitis, early intervention with ERCP reduces morbidity and mortality compared with delayed ERCP.
- ERCP with appropriate therapy is beneficial in selected patients who have either recurrent pancreatitis or pancreatic pseudocysts.
- Patients with type I sphincter of Oddi dysfunction (SOD) respond to endoscopic sphincterotomy (ES).
- Patients with type II SOD should not undergo diagnostic ERCP alone. If sphincter of Oddi manometer pressures are >40 mmHg, ES is beneficial in some patients.
- Avoidance of unnecessary ERCP is the best way to reduce the number of complications.
- ERCP should be avoided if there is a low likelihood of biliary stone or stricture, especially in women with recurrent pain, a normal bilirubin, and no other objective sign of biliary disease.
- Endoscopists performing ERCP should have appropriate training and expertise before performing advanced procedures.
- With newer diagnostic imaging technologies emerging, ERCP is evolving into a predominantly therapeutic procedure.

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