IAP Guidelines for the Surgical Management of Acute Pancreatitis

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Abstract
During 2002 the International Association of Pancreatology developed evidenced-based guidelines on the surgical management of acute pancreatitis. There were 11 guidelines, 10 of which were recommendations grade B and one (the second) grade A. (1) Mild acute pancreatitis is not an indication for pancreatic surgery. (2) The use of prophylactic broad-spectrum antibiotics reduces infection rates in computed tomography-proven necrotizing pancreatitis but may not improve survival. (3) Fine-needle aspiration for bacteriology should be performed to differentiate between sterile and infected pancreatic necrosis in patients with sepsis syndrome. (4) Infected pancreatic necrosis in patients with clinical signs and symptoms of sepsis is an indication for intervention including surgery and radiological drainage. (5) Patients with sterile pancreatic necrosis (with negative fine-needle aspiration for bacteriology) should be managed conservatively and only undergo intervention in selected cases. (6) Early surgery within 14 days after onset of the disease is not recommended in patients with necrotizing pancreatitis unless there are specific indications. (7) Surgical and other forms of interventional management should favor an organ-preserving approach, which involves debridement or necrosectomy combined with a postoperative management concept that maximizes postoperative evacuation of retroperitoneal debris and exudate. (8) Cholecystectomy should be performed to avoid recurrence of gallstone-associated acute pancreatitis. (9) In mild gallstone-associated acute pancreatitis, cholecystectomy should be performed as soon as the patient has recovered and ideally during the same hospital admission. (10) In severe gallstone-associated acute pancreatitis, cholecystectomy should be delayed until there is sufficient resolution of the inflammatory response and clinical recovery. (11) Endoscopic sphincterotomy is an alter-
native to cholecystectomy in those who are not fit to undergo surgery in order to lower the risk of recurrence of gallstone-associated acute pancreatitis. There is however a theoretical risk of introducing infection into sterile pancreatic necrosis. These guidelines should now form the basis for audit studies in order to determine the quality of patient care delivery.

Introduction and Purpose of Guidelines

The necessity for surgical intervention in patients with acute pancreatitis has been controversial for more than 100 years, varying between a conservative medical approach on the one hand and a surgical approach on the other. In the past 15 years there has been a great leap in knowledge of the natural history of acute pancreatitis [1–3] and at the same time major advances in imaging of the pancreas [4]. Thus it has become possible to classify the severity of the disease and to assess the evolution of pancreatitis in real time [5]. This has enabled the objective assessment of various new approaches designed with the objective of significantly reducing the mortality of this dreadful disease [6].

During recent years the management of acute pancreatitis has changed. This has been due particularly in response to the general availability of computed tomography, improved intensive care facilities, knowledge about the central role of pancreatic infection and refinements in surgical and other interventional techniques [1, 4–6]. The present guidelines of the International Association of Pancreatology (IAP) address the role of the surgical management of acute pancreatitis including the indications, the timing and the techniques of surgery. These guidelines describe the highest standards of the surgical management of acute pancreatitis based on currently published studies.

Methods of Formulation of the Guidelines

The Process

A preliminary manuscript that was based on an extended literature search (Medline and Cochrane Library) of published reports was prepared and key recommendations proposed. The evidence and key recommendations were discussed at a special symposium of the IAP (Acute Pancreatitis: Indications for Surgery – IAP Guidelines Development) held on June 22, 2002 during the joint meeting of the International Association of Pancreatology and European Pancreatic Club (June 19–22, 2002) in Heidelberg, Germany. During the symposium key note lectures were given followed by intense discussions on the following topics: natural history of necrotizing pancreatitis; when to be concerned about severe acute pancreatitis; the natural course of organ failure in acute pancreatitis; radiological and clinical indications for surgical intervention; the role of markers for monitoring disease progression; outcome of open necrosectomy; and the results of minimally invasive necrosectomy. Manuscripts representing the groups of invited speakers for the aforementioned presentations were submitted to Pancreatology for peer-review prior to publication and should be read in conjunction with the IAP Guidelines.

Each of the proposed recommendations was discussed and an initial consensus was reached. The process involved excluding proposed or introducing new recommendations and agreeing on the precise wording of each of the recommendations. The draft manuscript was amended accordingly. The guidelines were then distributed to the key clinicians for approval or for further modifications, with all agreeing on the final version. These guidelines were then sent to all members of the IAP Council (2002) for approval and/or modifications. All parties concerned approved the final guidelines. The list of clinicians who were directly responsible for these guidelines together with those who were consulted at a later stage of their production is given at the end. Finally the IAP Guidelines were submitted to Pancreatology for peer-review prior to publication.

Categories of Evidence

The present guidelines have been produced to conform to established evidence-based guideline criteria [7–10]. The strength of evidence used in the formulation of these guidelines was graded according to the following system:

- **Ia** = Evidence obtained from meta-analysis of randomized controlled trials.
- **Ib** = Evidence obtained from at least one randomized controlled trial.
- **IIa** = Evidence obtained from at least one well-designed controlled study without randomization.
- **IIb** = Evidence obtained from at least one type of well-designed quasi-experimental study.
- **III** = Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies and case studies.
- **IV** = Evidence obtained from expert committee report or opinions or clinical experiences of respected authorities.

Grading of Recommendations

The strength of each recommendation depends on the category of the evidence supporting it and is graded according to the following system:

- **Grade A** = Strong evidence that requires a meta-analysis of randomized controlled trials or at least one randomized controlled trial (evidence categories Ia, Ib).
- **Grade B** = Intermediate evidence, requires non-randomized clinical studies (evidence categories IIa, IIb, III).
- **Grade C** = Low evidence, requires evidence from expert committee reports or opinions or clinical experiences of respected authorities, in the absence of directly applicable clinical studies of good quality (evidence categories IV).
Clinical Course of Acute Pancreatitis

Mild Pancreatitis

Most episodes of acute pancreatitis (80%) are mild and self-limiting, subsiding spontaneously within 3–5 days. The mortality rate is less than 1% and these patients normally do not need intensive care treatment and pancreatic surgery [6, 11–13].

Recommendation 1: Mild acute pancreatitis is not an indication for pancreatic surgery (recommendation grade B).

Severe Pancreatitis

In 10–20% of the cases, however, severe disease develops and parts of the pancreas and surrounding tissue become necrotic. Severe pancreatitis, in general, progresses in two phases. The first 2 weeks after the onset of symptoms the disease is characterized by the systemic inflammatory response syndrome (SIRS). The release of proinflammatory mediators is supposed to contribute to the pathogenesis of SIRS-associated pulmonary, cardiovascular, and renal insufficiency. It is important to understand that SIRS in the early phase of severe pancreatitis may be found in the absence of significant pancreatic necrosis and is frequently found in the absence of pancreatic infection [14, 15].

Infection of pancreatic necrosis naturally develops during the second phase of the disease (most commonly in the 2nd and 3rd week after the onset of symptoms) and has been reported in as many as 40–70% of patients with necrotizing pancreatitis [16–18]. The risk of infection increases with the extent of intra- and extra-pancreatic necrosis [16, 19]. Even with the use of prophylactic antibiotic therapy (prescribed in the absence of proven sepsis), infection of pancreatic necrosis is still a major risk factor in severe pancreatitis, whilst sepsis-related multiple organ failure is the main life-threatening complication with a mortality rate of 20–50% [19–22]. It is estimated that infected pancreatic necrosis will develop in about one third of patients who have been placed on broad-spectrum antibiotics that penetrate the pancreas and have the appropriate spectrum of activity against the microorganisms commonly found in necrotizing pancreatitis. With increasing use of antibiotics there has been a relative shift from predominantly gram-negative bacteria towards a higher incidence of infection with gram-positive bacteria and fungi 2–3 weeks after the start of antibiotic therapy [3]. Several randomized controlled trials have provided evidence that prophylactic antibiotics may prevent the development of septic complications [23–25] or a reduction in mortality [26] in severe acute pancreatitis. Interpretation of the individual trials is not straightforward: all 3 trials that showed a reduction in pancreatic sepsis showed no difference in survival, perhaps because they were underpowered [23–25], and the 1 trial that showed a reduction in mortality had an uneven distribution of early deaths and no reduction in pancreatic sepsis [26]. Two meta-analyses based on these data [27, 28] showed a beneficial effect from prophylactic antibiotics, both with regard to the development of infection and mortality.

Recommendation 2: The use of prophylactic broad-spectrum antibiotics reduces infection rates in CT-proven necrotizing pancreatitis but may not improve survival (recommendation grade A).

Once pancreatic necrosis has developed, the differentiation between sterile and infected necrosis is essential for the management of patients. Fine-needle aspiration for bacteriology (FNAB) of pancreatic or peripancreatic necrosis has been established as an accurate, safe and reliable technique for the identification of infected necrosis [17, 29, 30]. FNAB can be guided by either computed tomography or ultrasonography and should be performed in patients who develop significant pancreatic necrosis and clinical signs of sepsis. The complication rate of this procedure is low [29, 30], with a very low incidence of serious complications such as bleeding or exacerbation of acute pancreatitis [31, 32]. Bacterial tests including gram staining and culture of the aspiration material have a diagnostic sensitivity and specificity of 88 and 90%, respectively [33]. It is important that only those patients who develop clinical signs of sepsis should undergo FNAB, since the procedure bears a potential risk of secondary infection [3, 6, 33].

Recommendation 3: FNAB should be performed to differentiate between sterile and infected pancreatic necrosis in patients with sepsis syndrome (recommendation grade B).

Management of Infected Necrosis

Proven infected pancreatic necrosis as well as septic complications directly resulting from pancreatic infection are indications for surgical treatment [6, 12, 34, 35]. The mortality rate for patients with infected pancreatic necrosis is higher than 30%, and up to 80% of fatal outcomes in acute pancreatitis are due to septic complications [16, 20, 36]. The conservative management of infected pancreatic necrosis associated with multiple organ failure has a mortality rate of up to 100% [37]. In contrast the surgical treatment of patients with infected pancreatic necrosis is
associated with mortality rates that are as low as 10–30% in some specialized centers [6, 38, 39].

Recommendation 4: Infected pancreatic necrosis in patients with clinical signs and symptoms of sepsis is an indication for intervention including surgery and radiological drainage (recommendation grade B).

Management of Sterile Necrosis

Whereas infected pancreatic necrosis is a clear indication for surgery, the management of sterile pancreatic necrosis is still a matter of controversy. Most patients with sterile necrosis respond to conservative non-surgical medical management [6, 38]. Nevertheless, some patients do not improve despite maximal therapy in the intensive care unit (ICU) and the role of surgery remains debatable in those patients who develop organ failure associated with sterile pancreatic necrosis [14, 40-44]. In a retrospective series of 172 patients with sterile necrosis [42], 62% of patients were managed surgically whereas the remainder was treated conservatively. The mortality rate was not significantly different between the 2 groups: 13.1% for the surgically treated patients and 6.2% for those treated non-surgically. The surgical group, however, was characterized by higher Ranson and Apache II scores and higher serum levels of C-reactive protein on admission. It was concluded that persistent or progressive organ complications despite maximal ICU treatment was an indication for surgery in patients with sterile necrosis. The experience of the Ulm group is that the extent of pancreatic necrosis is related to organ failure (and hence mortality) in sterile pancreatic necrosis, whilst the incidence of organ failure is relatively high in infected pancreatic necrosis regardless of the extent of pancreatic necrosis [19]. On the other hand the Boston (Massachusetts General Hospital) group have an equally low mortality for both infected and sterile pancreatic necrosis [39, 43]. These data suggest wide variations in the types of patients operated upon that cannot be adequately compared using the present systems of disease severity classification.

Fulminant acute pancreatitis is characterized by rapidly progressive multiple organ failure in the first few days following the onset of acute pancreatitis with a high probability of death despite ICU therapy. There is a poor outcome with both surgical and conservative therapies [45, 46]. In selected cases however, such as persistent organ complications or severe clinical deterioration despite ICU therapy, surgery may be indicated in sterile necrosis [42].

Recommendation 5: Patients with sterile pancreatic necrosis (FNAB negative) should be managed conservatively and only undergo intervention in selected cases (recommendation grade B).

Timing of Surgery

Patients with severe pancreatitis can progress to a critical condition within a few hours or days after the onset of symptoms. In the early course of the disease, patients are at high risk of death from cardiovascular or pulmonary failure. In the past, early surgical intervention was favored especially in the presence of deteriorating systemic organ function but mortality rates of up to 65% were experienced [45, 47, 48], questioning the benefit of surgical intervention within the first few days after the onset of symptoms.

At present, there is general agreement that surgery in severe pancreatitis should be deferred whilst patients continue to respond positively to conservative management. The rationale for delaying surgical therapy is to permit proper demarcation of pancreatic and peripancreatic necrosis to occur. The 3rd or 4th week after the onset of the disease is generally agreed to provide the optimal operative conditions for necrosectomy, with the effect of limiting the extent of surgery that is needed to facilitate debridement. This approach decreases the risk of bleeding and minimizes the surgery-related loss of vital tissue that predisposes to surgery-induced endocrine and exocrine pancreatic insufficiency. In the only prospective randomized trial comparing early (within 72 h of symptoms) with late (at least 12 days after onset) pancreatic resection/debridement in patients with severe pancreatitis, the mortality rates were 56 and 27%, respectively [48]. Although the difference did not reach statistical significance, the trial was terminated because of concern about the very high mortality of early surgery.

Recommendation 6: Early surgery within 14 days after onset of the disease is not recommended in patients with necrotizing pancreatitis unless there are specific indications (recommendation grade B).

Surgical Procedures

The aim of surgery in patients with necrotizing pancreatitis is to remove all areas of necrotic tissue including necrotic pancreatic tissue and any infected necrotic tissue. In so doing the risk of further complications may be minimized by reducing the progress of spreading necrosis and/or infection and the release of proinflammatory mediators. Unlike debridement, resection procedures such as partial or total pancreatectomy that also remove vital pancreatic tissue and/or healthy organs are associated with high mortality rates, as well as increasing the risk of
postoperative exocrine and endocrine insufficiency [45, 49–51].

The surgical techniques for the treatment of pancreatic necrosis are varied and the ideal method is still debated. Generally agreed principles of surgical management include an organ-preserving approach which involves debridement or necrosectomy, minimization of intra-operative hemorrhage and maximization of postoperative removal of retroperitoneal debris and exudate. Three techniques are available with apparently comparable results: (i) open necrosectomy with closed continuous lavage of the retroperitoneum [41, 52]; (ii) open necrosectomy that may or may not be staged with planned re-laparotomies followed by delayed primary closure and drainage or with multiple drainage and re-laparotomy as required [35, 43, 44], and (iii) open necrosectomy with open packing and planned re-laparotomies [53]. It is reported that these approaches are associated with a postoperative mortality of less than 15% but there has never been a trial that has ever prospectively compared these techniques.

Novel approaches to treat pancreatic necrosis have been introduced including percutaneous techniques using radiological guidance either alone or in combination with minimally invasive techniques [54–57]. Although several specialized centers have reported that patients with acute pancreatitis may be managed by percutaneous catheter drainage or percutaneous necrosectomy, many patients have required subsequent laparotomy to control sepsis [54–57]. It has been proposed that these minimally invasive techniques are most suited for a subgroup of patients with localized and/or well-organized pancreatic necrosis, but these different approaches can only be properly compared in randomized controlled trials.

**Recommendation 7:** Surgical and other forms of interventional management should favor an organ-preserving approach which involves debridement or necrosectomy combined with a postoperative management concept that maximizes postoperative evacuation of retroperitoneal debris and exudate (recommendation grade B).

**Gallstone-Associated Acute Pancreatitis**

In Western countries, acute pancreatitis is associated with the presence of gallstones in 40–60% of cases [12, 58]. There is strong evidence that gallstones initiate an episode of pancreatitis by temporary or persistent obstruction of the distal common bile duct orifice at the ampulla of Vater, although the exact pathogenesis of subsequent pancreatic inflammation remains unclear [59–61]. Once the diagnosis of gallstone pancreatitis is established, the further management will depend on the severity of the attack and the presence of obstructive jaundice and/or acute cholangitis [62–65].

**Endoscopic Retrograde Cholangiopancreatography and Endoscopic Sphincterotomy to Improve the Outcome from a Severe Attack**

It may be important to determine rapidly whether gallstones are the cause of a severe attack, since endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic sphincterotomy (ES) may ameliorate symptoms and the progression of the disease. Failure of the patient’s condition to improve within 48 h despite intensive initial resuscitation is considered by some to be an indication for urgent ERCP and ES in gallstone-associated acute pancreatitis [62, 63]. Both the United Kingdom and Hong Kong groups who undertook the first randomized controlled trials of ERCP and ES in gallstone-associated acute pancreatitis favor early intervention in severe acute pancreatitis regardless of the presence of obstructive jaundice and/or acute cholangitis.

The results of a 3rd randomized controlled trial of ERCP and ES in gallstone-associated acute pancreatitis from Germany suggested that ERCP and ES should be restricted to patients with biliary sepsis or obstructive jaundice and that, in the absence of these clinical features, severity alone was not an indication for ERCP and ES [64]. Why the results of the German trial differ from the other 2 trials [62, 63] remains a matter of debate [66, 67]. Given the lack of a clear consensus on this subject, no recommendation can be made on the use of ERCP and ES in severe gallstone-associated acute pancreatitis per se, although all are agreed that ERCP and ES are indicated in the presence of obstructive jaundice and/or acute cholangitis.

**Role for Emergency Surgery**

Kelly and Wagner [68] assigned 165 patients with acute gallstone-associated pancreatitis to early surgery (within 48 h after admission) or delayed surgery (more than 48 h after admission). Early surgery was associated with a much higher morbidity (83 versus 48%, respectively) and mortality rate (18 versus 12%, respectively) in patients with severe pancreatitis than delayed surgery. Although there is much that can be criticized about this trial, there is general agreement that open cholecystectomy with supraduodenal bile duct exploration and insertion of a T tube is an unacceptable emergency procedure in patients with severe gallstone-associated acute pancreatitis. It is widely accepted that whilst comorbidity is a major predeterminant of outcome from cholecystectomy,
this factor does not apply to the use of ERCP and ES [69].

If a patient has had an endoscopic sphincterotomy during the course of an attack of gallstone-associated acute pancreatitis consideration should be given to removing the gallbladder as these patients have a relatively high risk of subsequent gallbladder symptoms [70–74].

Surgery to Prevent Further Attacks

Recurrence of acute pancreatitis in patients with gallstones has been reported in 29–63% of cases if the patient is discharged from the hospital without additional treatment [75–77]. The rationale for cholecystectomy and clearance of the main bile duct in these patients is to prevent potentially avoidable recurrent biliary pancreatitis. The timing of cholecystectomy depends on the clinical situation. In mild gallstone-associated acute pancreatitis cholecystectomy should be performed as soon as the patient has recovered from the attack and preferably during the same hospital stay [12, 78, 79]. In severe gallstone-associated acute pancreatitis, cholecystectomy should be undertaken once the inflammatory process has subsided and with sufficient clinical recovery to make the procedure technically easier and safer for the patient [80–82]. Cholecystectomy can be performed safely after an episode of gallstone-associated acute pancreatitis has resolved by a laparoscopic approach [79, 80, 83]. The success rate of the laparoscopic approach is between 80 and 100%, with a conversion rate of between 0 and 16%.

Recommendation 8: Cholecystectomy should be performed to avoid recurrence of gallstone-associated acute pancreatitis (recommendation grade B).

Recommendation 9: In mild gallstone-associated acute pancreatitis cholecystectomy should be performed as soon as the patient has recovered and ideally during the same hospital admission (recommendation grade B).

Recommendation 10: In severe gallstone-associated acute pancreatitis, cholecystectomy should be delayed until there is sufficient resolution of the inflammatory response and clinical recovery (recommendation grade B).

Endoscopic Sphincterotomy to Prevent Further Attacks

Following an attack of either mild or severe gallstone-associated acute pancreatitis the patient may not be fit to undergo cholecystectomy. In these circumstances elective prophylactic endoscopic sphincterotomy (whether there are or are not any stones in the main bile ducts) is an important option. In 5 series with a total of 109 patients with median follow-up times of 22–39 months, only 1 (0.9%) developed a further attack of acute pancreatitis although 8 (7.9%) patients developed subsequent biliary symptoms [70, 72, 84–86]. There is a theoretical risk of introducing infection into sterile necrosis during the endoscopic sphincterotomy procedure although reports in the literature are lacking. In these circumstances complete resolution of the necrosis may be advised before undertaking the endoscopic sphincterotomy.

Recommendation 11: Endoscopic sphincterotomy is an alternative to cholecystectomy in those who are not fit to undergo surgery in order to lower the risk of recurrence of biliary pancreatitis. There is, however, a theoretical risk of introducing infection into sterile pancreatic necrosis (recommendation grade B).

Summary of the International Association of Pancreatology Audit Goals for the Surgical Management of Acute Pancreatitis

The following is a summary of the official IAP guidelines on the surgical management of acute pancreatitis. The grading of each recommendation is given and these are based on the evidence reviewed in the text. These guidelines should now form the basis for audit studies in order to determine the quality of patient care delivery.

1. Mild acute pancreatitis is not an indication for pancreatic surgery (recommendation grade B).
2. The use of prophylactic broad-spectrum antibiotics reduces infection rates in CT-proven necrotizing pancreatitis but may not improve survival (recommendation grade A).
3. FNAB should be performed to differentiate between sterile and infected pancreatic necrosis in patients with sepsis syndrome (recommendation grade B).
4. Infected pancreatic necrosis in patients with clinical signs and symptoms of sepsis is an indication for intervention including surgery and radiological drainage (recommendation grade B).
5. Patients with sterile pancreatic necrosis (FNAB negative) should be managed conservatively and only undergo intervention in selected cases (recommendation grade B).
6. Early surgery within 14 days after onset of the disease is not recommended in patients with necrotizing pancreatitis unless there are specific indications (recommendation grade B).
7. Surgical and other forms of interventional management should favor an organ-preserving approach, which involves debridement or necrosectomy com-
bined with a postoperative management concept that maximizes postoperative evacuation of retroperitoneal debris and exudate (recommendation grade B).

8 Cholecystectomy should be performed to avoid recurrence of gallstone-associated acute pancreatitis (recommendation grade B).

9 In mild gallstone-associated acute pancreatitis cholecystectomy should be performed as soon as the patient has recovered and ideally during the same hospital admission (recommendation grade B).

10 In severe gallstone-associated acute pancreatitis, cholecystectomy should be delayed until there is sufficient resolution of the inflammatory response and clinical recovery (recommendation grade B).

11 Endoscopic sphincterotomy is an alternative to cholecystectomy, in those who are not fit to undergo surgery in order to lower the risk of recurrence of gallstone-associated acute pancreatitis. There is, however, a theoretical risk of introducing infection into sterile pancreatic necrosis (recommendation grade B).

Acknowledgements

The following were participants at the IAP meeting to discuss the Guidelines on June 22nd 2002 and made active contributions to their formulation – Brazil: Jose Eduardo Cunha, Sonia Penteado (Sao Paulo); Bulgaria: Oleg Tcholakov (Sofia); Czech Republic: Peter Balaz (Prague); Denmark: Steen Larsen (Glostrup), Else K Philipson (Bispebjerg); Finland: Marko Lempinen (Helsinki); France: René Laugier (Marseille); Germany; Hans-Guenter Becker (Kaiserslautern), Pascal Berberat, Markus W. Büechler, Fabio F. Di Mola, Pier-Laugier (Bordeaux). The following IAP Council members reviewed and approved the final version of the IAP Guidelines: Prof. J.P. Neoptolemos, Liverpool, UK (President); Prof. A.L. Warshaw, Boston, USA (Past-President); Prof. S. Matsuno, Sendai, Japan (President-Elect); Prof. G. Robles-Diaz, Mexico (Treasurer); Prof. G. Robles-Diaz, Mexico (Co-Treasurer); Prof. A.L. Warshaw, Boston, USA (Past-President); Prof. C. Bassi (Verona, Italy); Prof. P. Bornman, Cape Town, South Africa; Prof. E. Domínguez-Monzo, Santiago de Compostela, Spain; Dr. C.F. del Castillo, Boston, USA; Prof. K. Inoue, Kyoto, Japan (Co-Treasurer); Prof. M.V. Singer, Mannheim, Germany and Prof. C.W. Imrie, Glasgow, UK (Co-Editors, Pancreatology); Prof. C. Bassi, Verona, Italy; Prof. P. Bornman, Cape Town, South Africa; Prof. E. Domínguez-Monzo, Santiago de Compostela, Spain; Dr. C.F. del Castillo, Boston, USA; Prof. K. Inoue, Kyoto, Japan; Prof. M. Lerch, Münster, Germany; Prof. P. Levy, Clichy, France; Prof. J.E. Montecino Cunha, Brazil; Prof. A. Pap, Budapest, Hungary; Prof. R. Pezzilli, S. Lazzaro di Savena, Italy; Prof. C. Pitchumoni, New York, USA; Prof. G. Robles-Diaz, Co Toriello-Guerral, Mexico; Prof. K. Satake, Youkouchi Ashiya, Japan; Prof. R. Schmid, Heidelberg, Germany; Prof. T. Shimosegawa, Sendai, Japan; Prof. M. Tempero, San Francisco, USA; Dr. G.G. Tsiotos, Athens, Greece; Dr. M. Vaccaro, Buenos Aires, Argentina; Prof. D. Whitcomb, Pittsburgh, USA; Prof. J. Wilson, New South Wales, Australia.

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