

Chapter 4. Future Research

- **Rigorous studies are required in order to reliably quantify the relative performance of diagnostic ERCP compared to alternatives. Existing studies do not consistently use common reference standards and frequently do not report tests of statistical significance. Thus assumptions about equivalence or difference among alternative diagnostic technologies are not supported by robust empirical evidence.**

The selection criteria for diagnostic studies included in this review eliminated lesser quality studies. Thus, included studies were relatively free of referral and verification biases; and blinded interpretation of ERCP and the comparison technology was commonly performed. Nonetheless, the available literature on diagnostic performance suffers from two notable deficiencies. The first is failure to consistently use an adequate reference standard for comparative studies; technologies known to have good performance characteristics should be agreed upon for use as common reference standards. Valid comparisons between diagnostic alternatives cannot be made in the absence adequate reference standards. The second is the failure to provide for adequate statistical power or to report tests of statistical significance. Based on the available literature, is not possible to make confident determinations about the equivalence or magnitude of difference in performance among alternative diagnostic technologies.

- **Comparative studies of alternative diagnostic and treatment strategies are urgently needed. It is imperative to use a comprehensive approach to outcomes assessment, taking into account the total burden of morbidity and resource utilization.**

ERCP differs from its diagnostic alternatives in that a treatment intervention can be performed at the same time also and that ERCP generally has higher complication rates. The decision to use ERCP rather than an alternative should not be based solely on diagnostic test characteristics. Comprehensive measures of patient outcomes that take into account short-term morbidity, as well as cure, are needed. In some settings, most obviously laparoscopic cholecystectomy, the ultimate clinical outcomes are likely to be similar regardless of diagnostic and treatment strategy. Strategies should be evaluated based on comprehensive measures of resource utilization and measures of the total burden of morbidity that incorporate all relevant short-term and long-term effects on health. Studies are needed that compare diagnostic and treatment strategies using rigorous observational or experimental designs.

- **Evidence on treatment of chronic pancreatitis or recurrent pancreatitis is sparse. Rigorously designed controlled trials are needed to assess the outcomes of treatment for this debilitating condition.**

Prospectively designed comparative studies have been performed in many of the clinical setting addressed by this systematic review, although methodological weaknesses frequently limited the quality of the available evidence. However, in the area of treatment for chronic or recurrent pancreatitis and abdominal pain, studies comparing treatment alternatives were practically nonexistent, leaving only case series and before-after studies of varying quality. Based on this deficiency in the current literature, evaluation of treatments for chronic or recurrent pancreatitis

is a priority topic for future research. As new topics are prioritized for future research, careful attention must be paid to study design so that the appropriate clinical questions are addressed in a rigorous fashion.

- **Risk factors for complications of diagnostic and therapeutic ERCP have been explored using multivariable model analysis. Such analyses generate hypotheses for reducing complications, but cannot demonstrate cause and effect. Thus, interventions intended to reduce complications should incorporate prospectively defined studies to evaluate the results.**

The multivariable analyses predicting patient, procedure, or operator risk factors for ERCP complications included in this report suffer from methodological weaknesses that give rise to unstable and potentially misleading results. Younger patient age, suspected sphincter of Oddi dysfunction, use of precut sphincterotomy, and lower operator case volume have been repeatedly associated with increased ERCP complication rates. These findings should be used in setting hypotheses for future research. Intervention programs modifying these identified risk factors to reduce complication rates should incorporate prospectively defined studies to confirm whether the interventions actually reduce complications and improve outcomes.