The International Position on Laparoscopic Liver Surgery

The Louisville Statement, 2008

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Objective: To summarize the current world position on laparoscopic liver surgery.

Summary Background Data: Multiple series have reported on the safety and efficacy of laparoscopic liver surgery. Small and medium sized procedures have become commonplace in many centers, while major laparoscopic liver resections have been performed with efficacy and safety equaling open surgery in highly specialized centers. Although the field has begun to expand rapidly, no consensus meeting has been convened to discuss the evolving field of laparoscopic liver surgery.

Methods: On November 7 to 8, 2008, 45 experts in hepatobiliary surgery were invited to participate in a consensus conference convened in Louisville, KY, US. In addition, over 300 attendees were present from 5 continents. The conference was divided into sessions, with 2 moderators assigned to each, so as to stimulate discussion and highlight controversies. The format of the meeting varied from formal presentation of experiential data to expert opinion debates. Written and video records of the presentations were produced. Specific areas of discussion included indications for surgery, patient selection, surgical techniques, complications, patient safety, and surgeon training.

Results: The consensus conference used the terms pure laparoscopy, hand-assisted laparoscopy, and the hybrid technique to define laparoscopic liver procedures. Currently acceptable indications for laparoscopic liver resection are patients with solitary lesions, 5 cm or less, located in liver segments 2 to 6. The laparoscopic approach to left lateral sectionectomy should be considered standard practice. Although all types of liver resection can be performed laparoscopically, major liver resections (eg, right or left hepatectomies) should be reserved for experienced surgeons facile with more advanced laparoscopic hepatic resections. Conversion should be performed for difficult resections requiring extended operating times, and for patient safety, and should be considered prudent surgical practice rather than failure. In emergent situations, efforts should be made to control bleeding before converting to a formal open approach. Utilization of a hand assist or hybrid technique may be faster, safer, and more efficacious. Indications for surgery for benign hepatic lesions should not be widened simply because the surgery can be done laparoscopically. Although data presented on colorectal metastases did not reveal an adverse effect of the laparoscopic approach on oncological outcomes in terms of margins or survival, adequacy of margins and ability to detect occult lesions are concerns. The pure laparoscopic technique of left lateral sectionectomy was used for adult to child donation while the hybrid approach has been the only one reported to date in the case of adult to adult right lobe donation. Laparoscopic liver surgery has not been tested by controlled trials for efficacy or safety. A prospective randomized trial appears to be logistically prohibitive; however, an international registry should be initiated to document the role and safety of laparoscopic liver resection.

Conclusions: Laparoscopic liver surgery is a safe and effective approach to the management of surgical liver disease in the hands of trained surgeons with experience in hepatobiliary and laparoscopic surgery. National and international societies, as well as governing boards, should become involved in the goal of establishing training standards and credentialing, to ensure consistent standards and clinical outcomes.

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Over the last 2 decades, laparoscopic surgery has evolved to become the approach of choice for many abdominal procedures. The index operation for this era was laparoscopic cholecystectomy, which was rapidly adopted around the world in the 1990s.

Other moderately sized abdominal operations followed, including laparoscopic hernia repair, splenectomy, adrenalectomy, antireflux surgery, and bariatric surgery. These procedures were adopted after studies with a low level of evidence (case series) demonstrated benefits such as less pain and shorter length of stay and recovery, without loss of efficacy of the procedure.[1–3] Laparoscopic colectomy had a delayed adoption because of the fear that the oncologic efficiency of the operation would be lessened, and possibly that pneumoperitoneum was associated with a higher rate of tumor implantation. This concern was dispelled by several randomized controlled trials.[4,5]

Laparoscopic liver operations vary in complexity and difficulty, but can be broken down into 3 categories: (I) biopsies and small wedge resections, (II) resections of the left lateral section or anterior hepatic segments (4b, 5, 6), and (III) hemihepatectomies, trisectionectomies and resections of the difficult posterior segments (4a, 7, 8). The last category of procedures will be referred to as major liver resections in this document. Laparoscopic liver surgery was first reported in 1993.[6–9] Over the past 15 years the first 2 types of resections were introduced into clinical practice based on case series, which demonstrated the usual benefits of minimally invasive procedures, without loss of efficacy of the operations. Therefore these laparoscopic liver procedures are well along the "adoption curve." However, it was not until Cherqui et al[10] reported a prospective cohort of 30 patients did many acknowledge that laparoscopic hepatic surgery was feasible. Since this initial report, several centers have reported large laparoscopic series containing, many hemihepatectomies, including right lobe hepatic resection for adult to adult living-related donation for transplantation.[11] However, laparoscopic major liver resections are still on the early part of the adoption curve.

In an effort to better define the state of the art and future challenges, a consensus conference was convened. The organizing committee selected 45 recognized experts from around the world with the most extensive published experience in both laparoscopic and open liver surgery. The meeting occurred on November 7 to 8, 2008, in Louisville, KY. In all, 300 attendees were present from 5 continents.

Invitees were asked to discuss specific aspects of laparoscopic liver surgery ranging from current operative techniques, efficacy, and safety, to training/credentialing issues, to its role in the management of specific liver diseases. Presentations were supplemented by panel discussions and open audience forums in an attempt to forge consensus in the more difficult areas. The minutes were recorded and a video recording made. Within each session 2 moderators were assigned to stimulate discussion of controversial points. The broad sections of the conference are outlined in Table 1. After the meeting, section leaders prepared summaries of each section and an interim document, which contained consensus statements, was produced. The document was then circulated electronically and edited. All of the listed authors then rereviewed and agreed to the content of the present document, including the summaries.

TABLE 1. Session Topics Discussed at the first World Consensus Conference on Laparoscopic Surgery held in Louisville, KY, November 7–8, 2008

Current status of laparoscopic liver surgery in the world
Laparoscopic liver surgery: standardized terminology
Anatomic considerations in laparoscopic liver resection
Indications for laparoscopic liver resection
Benign disease
Malignant disease
Metastatic colorectal cancer
Hepatocellular cancer
Laparoscopic live-donor hepatectomy
Operative approaches and laparoscopic-related morbidity
Patient safety issues with laparoscopic liver surgery
Economics and outcomes of laparoscopic liver surgery
Training and certification

TERMINOLOGY AND DEFINITIONS

The consensus conference used the terms pure laparoscopy, hand-assisted laparoscopy, and the hybrid technique to define laparoscopic liver procedures. In the pure laparoscopic procedure, the entire resection of the liver is completed through laparoscopic ports; hand-assist devices or working incisions are not used, although a small incision may be made for specimen extraction. Hand-assisted laparoscopy is defined by the elective placement of a hand port for the purpose of facilitating the procedure. The unplanned placement of a hand port in the course of a pure laparoscopic procedure, either because of an intraoperative complication such as hemorrhage or due to inability to make progress, should be called "pure laparoscopy with hand-port conversion." The hybrid technique is defined as a procedure, which is started as a pure laparoscopic, or a hand-assisted procedure but the resection is performed through a mini-laparotomy incision. In the hand-assisted variant it is that incision, which is used for the mini-laparotomy part (sometimes with a small extension). This technique has been most often used in laparoscopic right liver lobe donor hepatectomy.

Summary

Three terms should be used to describe laparoscopic liver resection: pure laparoscopy, hand-assisted laparoscopy, and the hybrid technique.

AN OVERVIEW OF CURRENT METHODS OF MINIMALLY INVASIVE LIVER RESECTION

European centers, especially in France, have led the application of laparoscopic liver surgery with early feasibility studies, case control studies, and technical reports.[12–18] French groups performing major hepatectomies and laparoscopic adult to pediatric live-donor hepatectomy generally use pure laparoscopy.[19] They have employed liver transection methods commonly used in open hepatic surgery including clips and ties, reserving staplers for larger vessels and pedicles. In United Kingdom the focus has been on controlled introduction of laparoscopic hepatic resection techniques. Hepatic surgery has been concentrated in specialty centers, and surgeons and units require certification by the National Health Service including qualifying sessions. In other European countries multiple centers have initiated laparoscopic liver surgery programs without a central reporting or certifying agency. Asian groups have preserved many traditional operative techniques to replicate open surgery and operate under a tightly controlled system limited to specialized hospitals.[20–22]

In Australia and North America, a variety of specialists have reported their experience, including transplant and hepatobiliary surgeons, surgical oncologists, and laparoscopic surgeons.[23–25] Surgeons from North America aggressively adopted the hand-assisted or hybrid approaches. Hepatic transection can be been performed using either electrosurgical devices to divide parenchyma, reserving staplers for larger structures, or staplers to divide parenchyma and major structures without the aid of portal triad clamping. Surgical transection can then be classified into 2 camps: (1) electrosurgical dissection and (2) stapler hepatectomy. These techniques of paren-

chymal transection vary considerably from the traditional use of clamp and crush or CUSA dissection with vascular and clip control.

Summary

As in open hepatic resection a number of different technical approaches for performing major laparoscopic liver resection have evolved. As in open liver surgery no single method of parenchymal transection has been shown to be superior.

EFFICACY AND SAFETY OF LAPAROSCOPIC MAJOR LIVER SURGERY

Laparoscopic liver surgery in and of itself is not a new technology. Rather laparoscopic liver resection is a merging of minimally invasive techniques with various techniques in liver resection. Over the last decade, standard techniques in liver resection have been diversified by device-driven advances, including ultrasonic dissectors, saline coagulation, radiofrequency ablation, and stapler parenchymal transection. In combination, these technical advances used for major laparoscopic liver resection are a significant innovation and must be assessed for both safety and efficacy.

The dissemination of major laparoscopic liver resection has been considerably restrained compared with other minimally invasive procedures such as laparoscopic cholecystectomy and Nissen fundoplication. This may reflect the higher level of complexity involved in this procedure or the limited dissemination of advanced laparoscopic techniques among a majority of liver surgeons. Despite the slow and cautious dissemination of this procedure, laparoscopic liver resection has become a standard procedure in many centers for small and moderately sized resections, such as for left lateral sectionectomy.

Recently published studies report that laparoscopic major liver surgery offers the same benefits over open surgery as with other forms of minimally invasive surgery. These benefits include less pain, better cosmesis, and shorter length of stay. Furthermore, the morbidity and mortality rates in these studies are equivalent to large case series of open major liver resection, while the oncologic goals of such resections are maintained. However, most available studies are single center case series with limited follow-up. Notably, these reports emanate from centers in which surgeons have a high level experience in liver surgery and in advanced laparoscopy. All consensus participants recognized the possibility that publication bias with failure to publish negative events might be contributing to an overly optimistic view of the procedure. Of particular concern was the fact that members of the group collectively were aware of several unreported deaths during laparoscopic liver resection, including one in a young woman undergoing left lateral sectionectomy for a benign condition.

Additional concerns were raised over the possible problem of venous gas embolism. Several cases of hemodynamic instability and patient mortality were discussed. Animal experiments confirmed that when CO_2 embolism does occur it can be detected by intraoperative transesophageal echocardiography and does not create significant hemodynamic instability. CO_2 embolism is actually much safer than air embolism because of the greater solubility of CO_2 compared with nitrogen. However, argon gas embolization was reported to be associated with significant intraoperative complications[26,27] with some advocating abandonment of this hemostatic method, while others noted its safe use during laparoscopy for over a decade. Despite these opinions, it was recommended that if used, it should be with extreme caution, for minor hemostasis (not for bleeding from a significant vessel) and leaving one port open for venting excessive gas pressure. There was also no agreement regarding use of sealants to minimize postoperative bleeding or adhesions.

Summary

Major laparoscopic liver resections have been performed with safety and efficacy equaling open surgery in highly specialized centers. However, there is a potential for this safety record to be compromised by too rapid a dissemination of this procedure. Safety could be compromised by inadequate methods of training, knowledge dissemination, and the lack of established standards to assess competency. Major laparoscopic liver surgery should proceed only when a reported degree of safety is published equivalent to open liver surgery. However, to date the safety and efficacy of minimally invasive liver resection have not been assessed in a rigorously controlled fashion (see final section on training and credentialing).

PATIENT SELECTION

Currently the proportion of laparoscopic liver resections ranges from 20% to 80% of the total volume of liver surgery performed at a particular center. Consensus indicated that the most favorable indications for the laparoscopic resection was a solitary lesions, 5 cm or less, located in peripheral liver segments 2 to 6. Several videos of "difficult" resections were reviewed with lesions located in posterior segments (1, 7, and 8), but this was not universally accepted as standard of care. Left lateral sectionectomy, anterior segmentectomies or wedge resections were the most widely applied procedures. Left lateral sectionectomy was found by all participants to be the most straightforward moderate sized laparoscopic procedure, and these was agreement that in experienced hands, laparoscopy should be the standard approach for this particular operation. Major liver resections (ie, right or left hemihepatectomies) were shown to be feasible but remain difficult procedures which should be reserved to experienced surgeons already facile with more limited laparoscopic resections. Patients with tumors which are either large (>5 cm), central, multiple, bilateral or with connections with the liver hilum, major hepatic veins or the IVC are not at the moment candidates for a laparoscopic approach in most centers; however, in some, very experienced centers, even these lesions in selected patients are addressed laparoscopically. Over time, with increased world experience, the number of centers taking these on will likely increase.

Summary

There was a consensus that laparoscopic liver surgery be limited to selected patients. The best indications for laparoscopic liver resection are in patients with solitary lesions, 5 cm or less, located in the peripheral liver segments (segments: 2–6). The laparoscopic approach to left lateral sectionectomy should be considered the standard of care. Although most types of liver resection can be performed laparoscopically, including major liver resections (ie, right or left hepatectomies), these should be reserved to experienced surgeons already facile with more limited laparoscopic resections.

CONVERSION: A COMPLICATION OR PRUDENT CARE?

There was universal acceptance that conversion should not be viewed as a complication. Conversion from pure laparoscopy to hand assist should be performed in certain circumstances, for instance to control bleeding or to complete a difficult hepatectomy. However, efforts should be made to control hemorrhage laparoscopically rather than emergently converting to open laparotomy. Conversion to a hand-assisted approach is often more orderly and controlled than conversion to a full laparotomy, potentially reducing the risk of further major hemorrhage and hemodynamic instability. The group stressed that the surgeon embarking on laparoscopic resection should be facile with laparoscopic suturing and other

techniques of laparoscopic hemorrhage control, negating the need to convert emergently. Additionally, major vascular injuries, although exceptional, may not allow time for conversion and require a surgeon with extensive laparoscopic training. Although these should be considered to be useful guidelines, ultimately, surgical judgment should be used in individual cases to determine the extent of conversion.

Several other techniques for vascular control were described from hemostatic agent application, bipolar electrocautery, argon beam coagulation (see above-this device should be used with caution), vascular clip application, stapler reapplication, to the use of a Koffron "quick stitch." Application of this premade suture was accepted as an excellent measure for hemostasis during major hepatectomy for both venous and arterial bleeding.

Summary

Conversion should be performed for lack of case progress and/or patient safety. In emergent situations, efforts should be made to control the bleeding before converting to hand assist or laparotomy, as significant time and blood loss can occur during the process of conversion.

SHOULD INDICATIONS FOR RESECTION OF ASYMPTOMATIC BENIGN HEPATIC LESIONS BE WIDENED?

The Consensus then addressed the potential effect of laparoscopic hepatectomy on the management of benign hepatic lesions. This was evaluated in light of the following: (1) incidental finding of benign asymptomatic liver lesions has become common, (2) hemangiomas and focal nodular hyperplasia can be diagnosed in most of cases by imaging alone and rarely require surgery, (3) adenomas are recognized to posses a potential for bleeding and malignant degeneration and most importantly (4) the consequences of an adverse event are magnified when a procedure is done for asymptomatic benign lesions.

Considerable time was spent discussing the subtypes of hepatocellular adenomas and their varying natural history, with some being more prone to bleeding and others to malignant degeneration.[28] Additionally, it was noted that lesions initially read as atypical focal nodular hyperplasias were now classified as telangiectatic variants of hepatic adenoma.[29] However, a new indication for benign lesion surgical resection was identified during the consensus in the Asian experience that of intrahepatic cholelithiasis. Clear association of chronic stone disease with malignant degeneration to cholangiocarcinoma in 10% of patients has been established, making surgical resection of these lesions warranted.[30]

Summary

Indications for surgery for benign hepatic lesions should not be widened. Unroofing of simple hepatic cysts should not be considered a liver resection and should not be included in the analyses of laparoscopic liver resection.

COLORECTAL LIVER METASTASES AND MINIMALLY INVASIVE LIVER SURGERY

Presentations by the Basingstoke Unit in England (**) and Memorial-Sloan Kettering group in New York, confirmed there is a significant patient population with metastases from colorectal cancer that may benefit from a laparoscopic approach. Surgical margins and survival data (**) from available series were observed to be within the expected range of those reported after an open approach in comparable patients. Nonetheless, there are currently no trials that clearly demonstrated that laparoscopic hepatic resections have equivalent long-term outcomes to open hepatic resection. Two theoretical reasons for concern include (1) will the negative margin rate be as good as in open resections and (2) will small metastases be missed during laparoscopy. To avoid these problems patient and lesion selection, as well as accurate preoperative staging will be of great importance.

Several aspects of therapeutic approaches were discussed. It was noted that higher response rates to newer chemotherapy options, such as oxaliplatin and bevacizumab, are being observed. Other concerns were advanced regarding inadequacies of radiofrequency ablation for the management of colorectal metastases. Data presented by the MD Anderson group from Houston, revealed that local recurrence rates for colorectal liver metastases following radiofrequency ablation exceed 30%, even for tumors less than or equal to 3 cm in size.[31] There was clear consensus that resection is the gold standard treatment for colorectal liver metastases. However, RFA has application when resection is not possible.

Concerns were also raised over the quality of hepatic parenchyma encountered at the time of surgical exploration and potential resection. It was agreed that the quality of liver parenchyma being encountered today was frequently compromised due to the effects of chemotherapy.

Summary

Resection (laparoscopic or open) was accepted as the gold standard treatment for colorectal liver metastases. Concerns with laparoscopic liver resection for colorectal metastases included a potential increase in positive resection margins and failure to detect occult lesions. In terms of the latter, patients selection and preoperative staging is of critical importance.

HEPATOCELLULAR CANCER AND MINIMALLY INVASIVE LIVER SURGERY

This discussion began with the recognition of the epidemic rise in Hepatitis C and Non-Alcoholic Steatohepatitis with its associated development of hepatocellular cancer. The recognition of this potentially dramatic rise in Hepatocellular carcinoma (HCC), reignited the controversy over the superiority of transplantation versus resection. To some extent, this point was made moot by the realization that there was a significant disparity between the availability of liver allografts and demand for liver transplantation.

Resection remains the first-line treatment for HCC in compensated cirrhosis in many centers. It was also recognized that anatomic resection was associated with less recurrence and better survival that wedge or tumorectomy resections. Data were presented suggesting that laparoscopic resection of small HCC is associated with reduced morbidity in cirrhotic patients as compared with open resection, especially with reduced occurrence of postoperative ascites.[12,16,17] Laparoscopic resection of small hepatocellular cancers in a cirrhotic liver is feasible and safe in experienced centers, and follow-up data from a French group suggested that the long-term oncological outcome has not been compromised by the laparoscopic approach compared with open resection.

Data from a randomized controlled trial suggests that radiofrequency ablation may be an acceptable alternative to resection for small solitary HCC, but this is still a controversy that needs to be resolved with further randomized controlled trials. However, laparoscopic resection can provide a means to assess histology, which may serve as a surrogate for tumor biology. Poor prognostic indicators include poorly differentiated tumors, presence of micro or macrovascular invasion, and satellites nodules. Recently, the Barcelona group proposed transplantation for those patients with unfavorable histologies while electing to observe those with favorable histologies.

However, this seemingly paradoxical proposal is far from being widely accepted. In North America, patients with heptocellular cancer are placed on the waiting list according to a chemical score (MELD) based on laboratory values including the total bilirubin, international ratio, and creatinine. To minimize their death on the waiting list, patients within the Milan Criteria are given extra points known as exception points. Even with these exception points waiting times can be as long as 1 year, often necessitating the use of resection or ablation as a neodajuvant treatment (bridging to transplantation). In Europe, as demonstrated by the Barcelona group, transplantation is reserved for unfavorable histologies or tumor recurrence after resection (salvage transplantation). Data from a French group confirmed salvage transplantation (transplantation for recurrent HCC after initial open or laparoscopic resection) was feasible in as many as 50% of the cases with an advantage to the laparoscopic approach which minimizes the incidence of postoperative adhesions and morbidity.[32] The French advocate that this experience justifies resection as the primary treatment modality for HCC with patients monitored closely for early diagnosis of recurrence and subsequent salvage transplantation.

Laparoscopic resection has been alternatively used in the United States. Laparoscopic resection can identify favorable histologies including well to moderately differentiated tumors, lack of vascular invasion, and encapsulation. Currently United Network of Organ Sharing (UNOS) is discussing the potential of providing exception points for resected hepatocellular cancer patients but decreasing the quantity of points added to their chemical laboratory score. This makes the concept of bridging (stabilizing tumor by resection therapy while waiting on the list) patients to transplantation more attractive.

Summary

When local resection for HCC is undertaken it should be an anatomic segmental resection (if possible from the standpoint of overall liver synthetic function), as this is associated with reduced local recurrence and should be used in favor of tumorectomy. There are several histologic features of hepatocellular cancers that have been associated with a favorable tumor biology. However, the persisting underlying liver disease dictates that post resection hepatocellular cancer patients carry a 40% to 90% recurrence rate making transplantation an appealing option. There was consensus that significant shortages in liver donation makes transplantation for all hepatocellular cancers unrealistic. Consensus was achieved that improved biologic analysis (genomic analysis) and patient stratification will be required to better direct therapy for hepatocellular carcinoma. Laparoscopy can be used to assist in diagnosis, staging, and treatment of HCC.

LAPAROSCOPIC LIVE-DONOR HEPATECTOMY FOR TRANSPLANTATION

The most controversial topic in liver surgery has been the performance of living donor hepatectomy. The mortality of this procedure has varied from 0.5% to 1.0% based on reporting and the hepatectomy performed: left lateral section, left hepatectomy, or right hepatectomy. Initial experience was with pure laparoscopic left lateral segmentectomy for liver allograft procurement for pediatric transplantation. With continued evolution of minimally invasive liver surgery this approach has been applied to adult to adult donor right hepatectomy. The hybrid technique has been used by all those who attempted the procedure in the United States and Japan. No mortalities have been encountered in laparoscopic live donor hepatectomy whether adult or pediatric. Complication rates are in the range of those reported with open living donor hepatectomies. The most concerning issue has been the incidence of hepatic artery thrombosis in pediatric recipients. The advantages of the laparoscopic approach over a small midline incision were discussed in the case of left lateral section donation.

Summary

Laparoscopic live-donor hepatectomy will remain the most controversial application of laparoscopic liver surgery and should only proceed in the confines of a worldwide registry.

RANDOMIZED TRIALS OR CENTRALIZED REGISTRY

Many minimally invasive procedures share common benefits, problems, and questions. It may be reasonably asked whether findings of high level trials of 1 laparoscopic procedure may be accepted as valid for other procedures. In the discussions, the North American laparoscopic colon resection trial was used as a model for potential prospective randomized clinical trials in laparoscopic liver surgery. The discussion focused particularly on the issue of a primary end point for a randomized trial. If a patient-safety end point were to be chosen, a very large trial would have to be done since the mortality of open major liver resection is only about 1% to 2%. As was witnessed in the laparoscopic colon trial, the time required to acquire and analyze this data was nearly 10 years.[5] Moreover, it would seem unnecessary to reproduce the colorectal trial to determine whether laparoscopy per se has a negative effect on oncologic outcome due to tumor implantation in incisions. In addition, the limited number of indications and the hetereogeneity of the pathologies involved would make it even more difficult. A trial based on oncologic outcome would have to be limited to either HCC or metastatic tumors which occur much less frequently than primary colon cancers–implying a time longer than 10 years to accrue data. However, a trial whose primary end point was resection margin status might possibly be performed on all malignancies, provided there was even representation of patients with chronic liver disease in each arm.

If a cost-end point were to be chosen, multiple cost analyses have already confirmed that operative expenses of laparoscopic procedure are greater due to the cost of technology and disposables; and despite this initial investment in the surgical procedure, shortened hospital stays and associated expenses may result in a cost benefit for the laparoscopic technique. Economically, there may be benefit related to the earlier return to function as a result of smaller incisions and more rapid recovery.

An efficacy trial could be done based on the question of minimally invasive benefits, however, there was doubt that such a question would be of sufficient importance to justify the expense and effort required to perform such a study. It is essentially unnecessary to prove over and over again that minimally invasive surgery has benefits on pain control and recovery time. It should be noted that although this was proven for laparoscopic cholecystectomy by randomized controlled trials, the results were completely obvious. As no one had ever seen a patient discharged on the day of surgery with a standard open procedure, this was a form of all or none effect which is in itself level 1 evidence.

Since safety seemed to be a critical concern, a registry was considered as a feasible alternative. In regard to patient safety, the question was not so much, whether major laparoscopic liver surgery is inherently less safe than open surgery (although that is still a valid question), but whether these procedures can be disseminated in such a way as to minimize learning curve effects. Registries have been effective, and in some cases more effective than randomized control trials in picking up uncommon but severe negative events, eg, the major negative outcome of laparoscopic cholecystectomy (bile duct complications) was not detected in the randomized trials but by large registries.[33] The utility of a prospective registry that was focused on

safety issues would be very dependent on broad surgeon participation. Since severe negative events are uncommon, omission of only a small number could provide a false-negative result. Therefore, the registry would have to be prospective, with preoperative enrollment of patients and clear designation of the operative plan, and whether pure laparoscopic, hand-assisted or hybrid technique was to be used.

Summary

There may be a role for a prospective randomized trial, but difficulties in defining the relevant study questions, the size of the study population and the length of time to perform the trial may make this impracticable. There was consensus that the understanding of the role and safety of laparoscopic liver surgery would be advanced through a cooperative patient registry.

CERTIFICATION AND CONTINUED EDUCATION

Certification and credentialing have become a significant concern worldwide. Several countries have demonstrated great resolve in containing innovations to specialized centers, and in some cases such as England, specialized training and clinical certification exams. There was agreement that laparoscopic liver surgery should be initiated only in centers in which the combined expertise in liver and laparoscopic surgery exists. However, there were no proposals regarding exact criteria that define this expertise. Definition of such criteria would be helpful in guiding centers interested in starting a program. The emphasis should be placed on avoidance of patient harm that is most likely to come from inexperience rather than safety issues inherent in the procedures.

Summary

Safe dissemination of laparoscopic liver surgery is the highest concern. National and international societies, as well as governing boards, should become involved in the goal of establishing training standards and credentialing to ensure a high and consistent clinical outcome.

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