

EDITORIAL

The effect of Guidelines in surgical decision making: The paradigm of hepatocellular carcinoma

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Summary

It is not inconceivable to envision surgeons, offering extended liver resection in patients beyond the Barcelona Clinic Liver Cancer (BCLC) staging system criteria with intermediate/advanced hepatocellular carcinoma (HCC), to be found negligent since extensive liver resection is correlated with increased morbidity compared to conservative or pal-

liative treatment. Given that no other classification system than BCLC has been adopted widely for HCC staging and treatment, a revision of the BCLC algorithm and clinical guidelines should be tailored using new molecular and clinical treatment algorithms, as well as including patient's preferences.

Introduction

Worldwide, hepatocellular carcinoma (HCC) is the third most frequent cause of cancer-related death and its incidence is increasing because of the chronic effect of viral infections and other known risk factors, such as alcohol, aflatoxin, and most recently, non-alcoholic fatty liver disease [1-4]. Current curative treatments include liver transplantation, surgical resection or percutaneous ablation that are able to achieve a long-term survival of more than 50% of the patients at 5 years; however, only a small group of patients with early-stage HCC is eligible for these therapies [5-8].

Thus, in the past decades, several HCC staging systems based on tumor burden and liver function have been proposed to guide therapeutic decisions [9-11]. The Barcelona Clinic Liver Cancer (BCLC) staging system has been validated by Western and Eastern groups [9,11] and has been

approved as guidance for HCC treatment algorithms by the European Association for the Study of Liver (EASL), the European Organization of Research and Treatment of Cancer (EORTC) and the American Association for the Study of Liver Disease (AASLD), but not by the main Asian associations for the study of liver diseases [9-11]. This staging system currently recommends curative treatments for very early- or early-stage HCC (BCLC stage 0-A), palliative therapies such as transarterial chemoembolization (TACE) for intermediate-stage HCC (BCLC stage B), sorafenib administration for advanced-stage HCC (BCLC stage C) and supportive care for end-stage HCC (BCLC stage D) [4]. According to the BCLC classification, liver resection should be performed only in patients with a small single HCC nodule without signs of portal hypertension (PH) or hyperbilirubinemia.

The outcomes of operating beyond BCLC

It is well-established that over the years, hepatobiliary surgeons have been constantly pushing the frontiers of resectability in patients with malignant liver tumors by introducing several strategies to minimize the risk of postoperative liver failure and expanding the resectability of liver lesions otherwise considered unresectable. According to recent surgical series, the 5-year overall survival rate after liver resection ranges from 61 to 91% with postoperative mortality approaching 0% [12,13]. Based on the BCLC classification, patients with multiple, large and macrovascular invasive HCC should undergo palliative treatments with unsatisfactory long-term results even if the lesion is resectable [14]. However, recent studies have reported that surgical resection can lead to good short- and long-term survival in these patients [15-18]. Moreover, a recent study discussed the need of treating patients with intermediate/advanced HCC beyond current guidelines, since these “suboptimal” candidates had a significantly better 5-year survival when compared with HCC patients offered other treatments or no treatment [19].

Currently, based on the BCLC algorithm, the EASL/AASLD guidelines exclude many patients from curative treatment, although they may benefit from liver resection. Therefore, BCLC classification has been criticized because it excludes many patients with multiple tumors and large tumors, as wide as those with macrovascular infiltration and PH, who could benefit from curative liver resection [20-22]. Recent improvements in surgical techniques and perioperative care have enhanced the feasibility and safety of liver resection with satisfactory long-term results in selected patients with early HCC with PH and with intermediate-advanced HCC [23-26].

The conception behind the establishment of Guidelines

The Institute of Medicine defines clinical practice guidelines (CPGs) as “statements that

include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options”[27]. CPGs are used by diverse stakeholders including patients, legislators and policy makers, insurance companies, litigators, health systems and surgeons, not only to make surgical care efficient, but also to hold practitioners accountable across different practice and geographic settings. Trust from surgeons and physicians in general is an important principle because guidelines set the *de facto* standard for medical practice and therefore influence clinical decisions about individual patients, practice measures, insurance coverage and reimbursement [27]. Surgical guidelines have gained widespread recognition because they offer the potential of improving surgical outcomes leading to higher standards of care. However, these outcomes will only be achieved if they are, indeed, implemented [28,29].

The decision of operating beyond the Guidelines

So the question is simple: What will be the price being paid by treating patients with HCC beyond the guidelines since we are already aware that “we are unable to cure all our patients”? Surgeons who are sceptical about the scientific basis of clinical guidelines have two choices: they can follow guidelines even though they suspect doing so will not fully benefit the patients, or they can ignore them and do what they believe is right for their patients, thereby risking professional censure and possibly jeopardizing their careers [30,31]. Theoretically, adherence to clinical guidelines by surgeons would reduce care variation, decrease unnecessary costs and improve quality. Surgeons rightly worry about their own exposure (both legally and financially) if they elect to deviate from published guidelines. Although CPGs may be beneficial to overall population health, they may not be the right approach on case-by-case basis [32]. However, there is a real concern

Table 1. Highlights of surgical malpractice trends

Nearly 50% of malpractice trials were against surgeons in 75 of the largest counties in the US (2001).

Less than one half (46%) of general surgeons who reported being sued for malpractice said that they had adhered to the standard of care and would not have changed a thing.

\$222,285 was the mean medical malpractice payments made due to surgery related malpractice in the US 2002.

General surgery reaches an annual claim of 15.3% in US and ranks 3rd commonest specialty in terms of claim in the UK and 4th in Greece.

Surgery-related deaths account 32,000 with a \$9 billion cost for US healthcare system.

Sources: Medscape Malpractice Report 2015: Why General Surgeons Get Sued, Carol Peckham, February 2, 2016; Bureau of Justice Statistics, US Department of Justice; 2002 Annual Report, National Practitioner Data Bank, US DHHS; Medical Defence Union in the UK.

Table 2. Measures for surgical protection when deviating from Guidelines

Counseling multidisciplinary panels before offering treatment
Better surgical training
Documentation-accurate phrasing
Patient informed consent
Activation of medical organizations or societies
Operating in hospital setting-specialist centers
Discussing more with patient and family

among surgeons that going against a CPG recommendation could potentially lead to litigation, especially in the setting of a negative outcome. So when, if ever, is it acceptable to go against CPG recommendations? In the courtroom, CPGs are sometimes used to help define the standard of care against which the reasonableness of the surgeon's actions will be judged. Under current legal practice, CPGs can be used as evidence of the standard of care. When not adhering to guidelines, the surgeon often faces increased scrutiny if complications occur and legal action is pursued (Table 1).

Is it easy to broaden the Guidelines?

Thousands of guidelines have been issued [32,33] and when promulgated by highly respected professional societies, they sometimes serve as de facto "standards of care" that may be used to devise institutional protocols, to develop measures of surgeon performance, and for insurance coverage decisions. Updating clinical guidelines is a complex process that includes identifying new evidence, assessing whether it has an impact on the recommendations and assessing whether an update is required [34]. Despite scant research, guideline programs endorse 3 to 5 years as a reasonable period after which guidelines should be reviewed [33,34]. This generic guidance is based on a study published more than 10 years ago that investigated how often guidelines needed to be updated [35]. A recent analysis of recommendation-level data showed that recommendations quickly become outdated (about 20% of the recommendations were out of date within 3 years) [33]. Recommendations with a high turnover, such as those on liver surgery field, are more likely to require an update than those with a low turnover, which suggests that fields with high research activity are likely areas in which effects are not conclusive or where alternative interventions are being developed [33]. Guideline developers should hence tailor their strategies accordingly. Previous work studying

the lifespan of systematic reviews showed that an updating signal appeared in 23% of the publications within 2 years [32].

Is there any solution or we are tilting at windmills?

Emerging data from current literature demonstrate a 12-15.3% rate of litigation in general surgeons, ranking as the 2nd most sued medical specialty [36,37]. And it is not abrupt to predict that surgeons who offer extensive liver resection beyond BCLC in patients with intermediate/advanced HCC will be found negligent since extensive liver resection is correlated with increased morbidity compared to conservative or palliative treatment [19]. Consequently, BCLC guidelines should be revised and patients with intermediate/advanced stage HCC, when technically resectable, should receive the opportunity to be treated with radical surgical treatment and surgeons will be protected to be found negligent.

So, how do hepatobiliary surgeons best protect themselves when intentionally deviating from guideline recommendations? The answer is obvious: documentation. The more carefully surgeons document their decision making, including guidelines referenced, options discussed with the patient (including risks and benefits of each) and specific reasons for taking a particular approach (including patient preferences and unique circumstances), the more protected they ultimately will be [38]. The most contentious legal issues arise when there is a paucity of documentation, so the physician is forced to recollect a decision-making process that occurred often years earlier to defend the reasonableness of the care provided. In some cases, we expect that the value judgments that surgeons make are shared by their patients. But sometimes surgeons' values differ in important ways from those of many patients. When such value judgments are incorporated into professional treatment guidelines, without any explicit acknowledgment that a reasonable patient might choose an alternative course of treatment, they take potential choices

away from patients [39,40].

Good decision making requires familiarity with decision relevant facts and recognition of the values relevant to weighing the pros and cons of the alternatives. We recommend documenting the discussion with the patient in as much detail as possible, as well as explaining in the medical record the rationale for the clinical decision. There has been increased emphasis in recent years on personalized medicine and shared decision making [41], which runs counter to the standardized approach typically espoused by guidelines (Table 2).

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Conclusions

Nowadays, no other than BCLC HCC classification has been approved worldwide and the treatment strategy should be tailored on the single patient, based on literature data. Thus, a revision of the BCLC algorithm and clinical guidelines should be introduced possibly including new molecular and clinical classifications.

Conflict of interests

The authors declare no conflict of interests.

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