Influence of Transfusions on Perioperative and Long-Term Outcome in Patients Following Hepatic Resection for Colorectal Metastases

To the Editor:

We read with interest the article by Kooby et al on the influence of transfusions on perioperative and long-term outcome in patients following hepatic resection for colorectal metastases.[1] The study, which has analyzed blood transfusion records and clinical outcomes for 1351 patients undergoing liver resection at a tertiary cancer referral center, shows that transfusion is an independent predictor of operative mortality, complications, major complications, and length of hospital stay but is not associated with adverse long-term survival. However, this article did not give attention to the relationship between timing of transfusion and postoperative clinical outcome.

Recently, in collaboration with the Department of Surgery of the Autonomous University of Barcelona, we conducted a retrospective study that investigated whether perioperative blood transfusions significantly affected postoperative septic morbidity and mortality in patients undergoing elective surgery for gastric cancer.[2] Our study has shown that stratifying patients according to timing of transfusion, postoperative mortality and septic morbidity were similar in patients who did not undergo transfusion (3.7% and 22.2%, respectively) and in patients who received transfusion exclusively preoperatively and/or perioperatively (3.9% and 20.5%, respectively), whereas they were significantly higher in patients who underwent postoperative transfusion, with or without receiving preoperative or perioperative transfusion (31.4% and 72.2%, respectively, $P < 0.01$). Moreover, postoperative but not preoperative and/or perioperative transfusion was an independent prognostic factor in multivariate analysis (odds ratio, 17.5; 95% confidence interval, 5.8–52.8). We also observed that in most patients who received postoperative transfusions, septic complications preceded or were simultaneous with transfusion, and transfusion was administered in the absence of clinical evidence of bleeding. Therefore, we suggested that extracellular fluid expansion (leading to hemodilution and a low hemoglobin value) during stress response in patients who were developing or had just developed septic complications may act as a confounder and may be considered responsible for the association between postoperative transfusion and septic morbidity. In other words, it seems that it is not blood transfusions themselves, but the circumstances necessitating transfusions that are the real determinants of prognosis. This does not mean that an immunosuppressive effect of allogenic blood transfusion does not exist, but only that it may not be clinically relevant with respect to postoperative infectious complications.

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The NIH Criteria for Parathyroidectomy in Asymptomatic Primary Hyperparathyroidism

Are They Too Limited?

To the Editor:

We read with interest the recent report by Dr. Eigelberger and colleagues.[1] In this article, the authors describe the National Institutes of Health (NIH) criteria for parathyroidectomy in asymptomatic primary hyperparathyroidism as being too limited.

Over a 3-year period, the authors compare the frequency of preoperative and postoperative symptoms and conditions related to primary hyperparathyroidism between 103 patients who met the NIH criteria and 75 patients who did not. A few questions and comments arise from this manuscript.

1. The indications/criteria used by the authors for parathyroidectomy in patients who do not meet the NIH criteria should be clearly stated.
2. How many non-NIH criterion patients had preoperative normal serum calcium levels? If the group contained patients with "normocalcemic hyperparathyroidism," how do you follow such patients in the postoperative period? This question becomes important because up to 17% of patients with normocalcemia will have elevation of iPTH 6 months after parathyroidectomy.
3. The average postoperative follow up was only 1 month. How many patients were followed for at least 6 months in that this length of follow up will assure that persistent disease was not missed? Follow up of symptoms and associated conditions along with biochemical confirmation would be informative at 6 months and evidence of a curative parathyroidectomy.

To illustrate these questions, we pose the following commonly seen patient.

A 65-year-old woman is referred to the reader with mild hyperparathyroidism, osteopenia, constipation, and depression. Her highest preoperative calcium is 10.2 mg/dL (range, 8.7–10.1 mg/dL), normal urine calcium, and iPTH of 80 pg/mL (range, 10–65 pg/L). Based on this article, this patient is subjected to parathyroidectomy. After surgery, her calcium and iPTH are within normal range. If, however, after 6 months of follow up, her iPTH is 70 and her calcium 10.1, would she be considered cured of primary hyperparathyroidism based on the improvement in her constipation and depression?

We believe parathyroidectomy will improve symptoms and associated conditions in patients with primary hyperparathyroidism. However, operating on patients without clear biochemical indications may lead to an increase in the inappropriate use of this operation and diminish its positive returns.

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Differences in Completion of Screening Logs Between Europe and the United States in an Emergency Phase III Trial Resulting From HIPAA Requirements

To the Editor:

We read with interest the article by O'Herrin et al[1] in which they described the increase in workload for healthcare centers and researchers and the increase of dropout rate for proposed studies when investigators are unable or unwilling to meet the regulatory requirements as the result of the current privacy regulation. The requirements of the Health Insurance Portability and Accountability Act (HIPAA), implemented in the United States on April 14, 2003, have changed the use of identifiable private health information (PHI).[2] Research affected by the HIPAA regulations includes medical record review. Although intentioned to protect patient privacy, the privacy rule assembles significant barriers to the use or disclosure of general health information.

As coordinating quality control and assurance center for an international multicenter phase III trial on the safety and efficacy of a neuroprotective agent in traumatic brain injury (TBI), we have noted significant differences in completion of screening logs between European and U.S. centers as a result of the HIPAA requirements. All European, but only 5 of 15 U.S. sites report age in actual years, with the remaining 10 U.S. sites only dividing patients into 3 categories: $<$18 years, 18–65 years, and $>$65 years of age, the middle category being an inclusion criteria and the other 2 exclusion criteria. Actual age is considered PHI. European screening logs indicate the exact time of injury in hours and minutes; 10 American sites only mentioned the date of injury. Information on the occurrence of hypoxic or hypotensive episode is requested in the screening logs, but many American sites do not complete this for reasons of PHI, and likewise, the admission Glasgow Coma Scale is often omitted. These features are pertinent toward enrollment criteria, and whether or not exclusion of the patient from the trial was appropriate can only be determined from fully completed screening logs.

Furthermore, comparison of participating and nonparticipating screened patients, or comparison of basic population characteristics between countries and regions, is not possible when all characteristics with some relation to PHI are withheld on the screening logs.

The original CONSORT (Consolidated Standards of Reporting Trials) statement was developed by investigators, epidemiologists, statisticians, and editors of peer-reviewed biomedical journals in the mid-1990s and revised recommendations published in 2001.[3,4]

The CONSORT statement outlines procedures for reporting results of a randomized, controlled clinical trial in a transparent manner, and includes a checklist and flow diagram for reporting clinical trials. This includes the number of patients excluded and reasons for exclusion. As a result of the strict HIPAA requirements, we are certain that the data of screening logs from U.S. sites in this phase III trial preclude possibilities for checking accuracy of exclusion and are not compatible with the outlines for reporting a well-conducted trial according to CONSORT. It is further remarkable that two thirds of U.S. sites do not provide any PHI, but one third appear to apply the regulations less strictly.

We hold the opinion that the use of some PHI for completion of screening logs should be permitted under an alternation or waiver of authorization requirements with approval from an Institutional Review Board.

There is a minimal risk to the privacy of individual subjects when these data are used in screening logs, but the quality of the trial is negatively affected if such data are not provided.

Only high-standard trials can prove the potential benefit of new treatments, and, in this specific scenario, the defense of the privacy collides with the quality of research.

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Evaluating Obesity Before Surgery

In Reply:

I think the content of the letter is interesting, and an accurate and practical method of evaluating obesity before surgery is helpful *for* many surgeons. I agree that the distribution of intraabdominal fat is important to insight surgical difficulties. Actually, we also know that there are 2 types of obesity; one is rich in subcutaneous fat and the other is rich in intraabdominal fat, mainly of the greater omentum. Laparoscopic gastrectomy for the former group of patients is affected by difficulty in the Billroth I reconstruction through a minilaparotomy incision, sometimes resulting in extension of the incision. In surgery of the latter group of patients, the laparoscopic view tends to be interfered by excessive intraabdominal fat tissues, leading to conversion to open surgery in some cases. Contrast of the 2 types in the figures displayed by Dr. Kawamoto is striking despite the relatively low body mass index (2.40 kg/m^2). The subcutaneous type is often observed in females and the intraabdominal type in males. Although that tendency has not been fully documented yet as a result of the small number of patients with an "intraabdominal fat area" of more than 200 cm^2, we have often encountered the event and discussed a little about the sexual difference in our manuscript. We have experience with laparoscopy-assisted distal gastrectomy (LADG) in more than 150 patients. The technical proficiency has reduced requirements of an open conversion and extension of the minilaparotomy incision even in obese patients. However, prolonged operative time and delayed recovery of bowel activity are still observed in obese patients. The difficulties in performing laparoscopic surgery still remain in obese patients. Information obtained from computed tomography (CT) scans would be very helpful in the assessment of surgical difficulty. If the area of fat tissue can be calculated more easily by the CT scans, it will certainly be a benefit to many surgeons on the initial learning curve of laparoscopic surgery. However, the criteria proposed by Dr. Kawamura that the fat area of 200 cm^2 on the CT image at the umbilical level is critical would be modulated by experience and technical proficiency of surgeons.

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Laparoscopic Roux-en-Y Gastric Bypass, But Not Rebanding, Should Be Proposed as a Rescue Procedure for Patients With Failed Laparoscopic Gastric Banding

To the Editor:

In the December 2003 issue of the *Annals of Surgery*, Weber et al[1] concluded that conversion to Roux-en-Y gastric bypass should be considered as the rescue therapy of choice after failed laparoscopic gastric banding. In the "Patients and Methods" section of this paper, it is stated that "The rebanding procedure was then performed when patient refused to undergo a Roux-en-Y gastric bypass, often due to its irreversibility." The same argument is stressed in the Discussion section (Dr. Weber's reply to Dr. Harder's question). We do not agree entirely with the fact that Roux-en-Y gastric bypass is an irreversible procedure.

First, reversal of Roux-en-Y gastric bypass is technically feasible by anastomosing the proximal gastric pouch to the remnant stomach and reversing of the Roux-en-Y loop.[2] In fact, this procedure is rarely done certainly because of its efficacy in achieving weight loss. On the other hand, reversal of Roux-en-Y gastric bypass may be technically demanding and is certainly more invasive than removal of a gastric band that is generally done laparoscopically.

Second, any bariatric procedure should be meant as definitive because its reversal is invariably followed by weight gain or persistence of the obesity.[3] As a consequence, the easy reversibility of a given procedure should not be considered as a determining argument against the use of a more adapted but less easily reversible procedure. Third, although at this time nonsurgical treatment of morbid obesity is not effective in long-term weight loss, it may be possible that in the future this condition will be treated conservatively. It may be speculated that, in this case, a bariatric procedure reversal including Roux-en-Y gastric bypass will become more common.

We think that the concept of irreversibility in bariatric surgery is of paramount importance and should be used with care when dealing with morbidly obese patient candidates for a bariatric procedure.

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Laparoscopic Roux-en-Y Gastric Bypass, But Not Rebanding, Should Be Proposed as a Rescue Procedure for Patients With Failed Laparoscopic Gastric Banding

In Reply:

We thank Drs. Iannelli and Guggenheim for their interest in our study and their 3 comments. First, they question our statement about the irreversibility of a gastric bypass procedure. Although we agree that this complex procedure is theoretically reversible, to our knowledge, this approach has not been published yet. The quoted paper by Curry et al does not describe the reversibility of a transected Roux-en-Y gastric bypass. Therefore, to emphasize the extensiveness of the Roux-en-Y gastric bypass, we currently present Roux-en-Y gastric bypass as a definitive procedure to our patients. We fully agree with the second point that any bariatric procedure should be proposed to the patient as a definitive solution as weight gain or persistence will inevitably recur after reversal. Third, whether reversal of Roux-en-Y gastric bypass may become common once morbid obesity can be cured with conservative measure remains speculative. Such a high-risk procedure may not be justified in patients with well-controlled weight and good quality of life.

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