

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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REFERENCE

1. Eigelberger MS, Cheah WK, Ituarte PHG, et al. The NIH criteria for parathyroidectomy in asymptomatic primary hyperparathyroidism: are they too limited? *Ann Surg.* 2004;239:528–535.

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 al¹ in which they de-

scribed 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 intended 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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REFERENCES

1. O'Herrin JK, Fost N, Kudsk KA. Health insurance accountability act (HIPAA) regulations. Effect on medical record research. *Ann Surg.* 2004;239:772-778.
2. Kulynych J, Korn D. The effect of the new federal medical-privacy rule on research. *N Engl J Med.* 2002;346:201-204.
3. Begg CB, Cho MK, Eastwood S. Improving the quality of reporting of randomised controlled trials: the CONSORT statement. *JAMA.* 1996; 276:637-639.
4. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomised trials. *Lancet.* 2001;357:1191-1194.

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/m²). 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 cm², 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 cm² 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 al¹ con-

cluded 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.