

COMMENTS AND RESPONSES

Care Management for Heart Failure

TO THE EDITOR: Contrary to popular belief, the randomized, controlled trial is not bias-free. The paper by DeBusk and colleagues (1) highlights a potential threat to validity, the Hawthorne effect, that the authors do not recognize. The medical staff at the 5 Kaiser Permanente hospitals were informed of the study protocol. Considering that Kaiser Permanente is a closed system of care, we do not know if physicians behaved differently because they were aware that they would be indirectly scrutinized for the care they provided. One assessment that could provide insight into this issue would be to indicate the population-wide change in use of angiotensin-converting enzyme inhibitors and β -blockers among all patients with congestive heart failure, in addition to just the intervention and control groups. As it stands now, the reader is left to wonder whether the Hawthorne effect in the control group negated the potential positive effects of disease management services in the intervention group.

Second, and potentially more important, telephone-based disease management is intended to guide participants toward improving control of their condition by bringing individuals and their physicians in line with evidence-based practice guidelines. If in fact most individuals already adhere to self-management behaviors—as seems evident in DeBusk and colleagues' study—little gain can be expected from a disease management program.

For these 2 reasons, the external validity and generalizability of this study are unknown. Thus, the authors' conclusion that the benefits of disease management may not be valuable to low-risk patients elsewhere is overreaching. An equally valid conclusion, with stronger internal validity, would be that a telephone-based disease management strategy does not appear to work in a tightly controlled, well-managed, low-risk sample of patients with congestive heart failure.

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Reference

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IN RESPONSE: Drs. Linden and Wilson note that physicians' awareness of our study may have influenced the care provided to study participants. However, any such effect was substantially mitigated by the fact that our study was conducted by an "outside" group of Stanford-based investigators without the incentive or means to provide feedback to Kaiser Permanente physicians or administrators about the quality of care provided. Given the nature of the excluded patients, an analysis of changes in medication prescription rates in this group would be difficult to interpret. As Drs. Linden and Wilson suggest, the evidence-based "baseline" care provided by Kaiser Permanente physicians for low-risk patients with heart failure might

not have been amenable to improvement. However, our group has conducted a series of multicenter randomized trials in Kaiser Permanente hospitals in which care management produced superior outcomes (1–4). These trials focused on behaviors (exercise, smoking, diet, drug adherence) that were under the direct control of patients. As we noted in our paper, rehospitalization is only partly influenced by patients' adherence to medication regimens for heart failure. Indeed, most rehospitalizations in our study were not for heart failure but for coronary artery disease and other medical conditions. This underscores the need to address the multiple comorbid conditions associated with chronic diseases (5). We agree with Drs. Linden and Wilson that our study was not designed to evaluate the generalizability of our findings to settings other than health maintenance organizations (HMOs). Regarding the value of disease management in low-risk patients treated elsewhere, our conclusions speak for themselves: "Although nurse care management did not statistically significantly reduce the rate of rehospitalization compared with the Kaiser Permanente HMO-treated group, its potential value in non-HMO settings should not be diminished."

Drs. Linden and Wilson raise an interesting methodologic problem with evaluating nurse care management: Such studies rely on physicians' willingness to collaborate closely with the nurse care managers. It is our impression that physicians practicing in HMO settings are more willing to do this than those practicing in other settings. A future challenge is how to organize and conduct rigorous studies of care management for various chronic conditions outside of environments such as HMOs, where physicians place a high value on collaboration.

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Angiotensin-Converting Enzyme Inhibitors and Angiotensin-Receptor Blockers in Chronic Heart Failure

TO THE EDITORS: As noted in Lee and colleagues' meta-analysis (1), the evidence for use of angiotensin-receptor blockers (ARBs) for chronic heart failure and acute myocardial infarction (MI) with left

ventricular systolic dysfunction has evolved, and relevant performance measures now need to be revised. The Centers for Medicare & Medicaid Services (CMS) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have been working toward this goal with the American Heart Association, the American College of Cardiology, and the Heart Failure Society of America since the publication of the VALsartan In Acute myocardial iNfarctiOn (VALIANT) trial (2) and the Candesartan in Heart failure Assessment of Reduction in Morbidity and mortality (CHARM) trial (3). In response to this growing body of evidence, CMS and JCAHO have concluded that ARBs should no longer be excluded from measures of quality care in the treatment of these conditions and have agreed to change the angiotensin-converting enzyme (ACE) inhibitor performance measures for acute MI and heart failure, effective 1 January 2005.

Several clinical practice guidelines still recommend ACE inhibitors as the first choice of therapy because of the greater amount of evidence and recommend ARBs only in ACE-intolerant patients (4–6). However, the new guidelines for ST-segment elevation MI give ARBs a class IIa recommendation, indicating that the weight of evidence favors their use as an alternative to ACE inhibitors. With the support of the evidence and the guidelines, JCAHO and CMS—at a summit of stakeholders sponsored by the Agency for Healthcare Research and Quality and the National Quality Forum on 3 November 2004—proposed revised measures for acute MI and heart failure that would allow the prescription of either ACE inhibitors or ARBs to satisfy the measure. The revised measures were supported by the American Heart Association, the American College of Cardiology, the Heart Failure Society of America (7), the National Committee for Quality Assurance, and the Agency for Healthcare Research and Quality and were endorsed by the National Quality Forum.

Because the science of measuring performance in health care is relatively new, there are currently no explicit rules for changing an accepted measure in response to advances in research. Assuring that measures reflect current scientific knowledge is imperative. One of the most remarkable aspects of the aforementioned measure-revision process has been the process itself, which has required a closely integrated effort on the part of the many organizations that have been involved in the definition and endorsement of these measures. The relatively timely implementation of these updated measures became possible only through the collaborative effort of many organizations committed to high-quality care.

The measure change will be accomplished in 2 phases because of practical reasons related to the feasibility of making rapid changes in measure software used around the United States. Beginning with discharges on 1 January 2005, the CMS and JCAHO data dictionary will be changed to capture any discharge prescription for an ACE inhibitor or an ARB as meeting the intent of the measure. A notation of “contraindication to both ACE inhibitor and ARB” will exclude patients from the measure. It is anticipated that the change will be fully implemented in fall 2005 and will capture ACE inhibitors and ARBs separately, along with separate exclusion criteria for “contraindication to ACE inhibitor” and “contraindication to ARB.”

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TO THE EDITOR: It would be remiss not to draw attention to the dosing of the ACE inhibitors and ARBs in the article by Lee and colleagues (1). In recent ARB trials that were newly incorporated into Lee and colleagues' meta-analysis, much higher doses of ARBs were used than in previous trials. Earlier comparison trials showing trends toward superiority of ACE inhibitors over ARBs used routine doses of the former but lower doses of the latter (2, 3). When ACE inhibitors and ARBs are used in the higher doses examined more recently, ARBs appear to become a suitable alternative to ACE inhibitors (4, 5). For example, the Optimal Trial In Myocardial Infarction with Angiotensin II Antagonist Losartan (OPTIMAAL) and the VALIANT trial compared losartan, 50 mg/d, and valsartan, 320 mg/d, respectively, with captopril, 150 mg/d.

The volume of evidence favoring ACE inhibitors in both chronic heart failure and acute MI is vastly greater than that for ARBs, and current JCAHO quality indicators should remain unchanged. Intolerance to ACE inhibitors necessitating ARB use affects a relatively small population and would probably not lead to a significant increase in indicator measure numbers.

Current congestive heart failure recommendations from the American College of Cardiology and the American Heart Association suggest that several ACE inhibitors should be tried if ACE inhibitor-induced cough is suspected. Quality indicators are meant as a measure and comparison of an institution's implementation of evidence-based best practices. Moreover, current ARB product labeling and monograph information, except for valsartan, do not state the higher dosing required in chronic heart failure or acute MI, but rather contain the lower dosing suggestions for hypertension. In addition, in simple economic comparisons, when ARBs are used in these higher doses (and assuming comparable efficacy to ACE inhibitors), the difference in medication cost vastly favors ACE inhibitors by a 10-fold margin. Subtherapeutic ARB dosing is a potential problem, especially among practitioners not familiar with this specific study literature. While ACE inhibitor use is improving throughout the United States and providers are becoming more familiar with target doses, routine use of ARB therapy seems fraught with errors at present.

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TO THE EDITOR: Lee and colleagues' meta-analysis on ARBs (1) appears to have missed 2 points that could be important for optimizing patient outcomes. First, in the post-MI setting, the target dosage for valsartan in the VALIANT trial was 160 mg twice daily (2), much higher than the dosage of 80 mg twice daily reported by Lee and colleagues in their Table. The captopril dosage was 50 mg 3 times daily. (Mean dosages at 1 year were 247 mg/d in the valsartan group and 117 mg/d in the captopril group, both clearly above the "target" dosages reported in the meta-analysis.) Dosing considerations are important because in the earlier OPTIMAAL, losartan, 50 mg/d, had worse cardiovascular death outcomes than captopril, 50 mg 3 times daily (3). One proposed explanation for this was that the losartan dose may have been too low. On the basis of the few outcome trials to date, it appears that higher doses of ARBs may be needed in the post-MI setting if we are to consider these agents equivalent alternatives to ACE inhibitors.

A second item of note is the lack of additional outcome benefit but the increase in adverse events for the combination arm (valsartan plus captopril) of the VALIANT trial.

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IN RESPONSE: We are pleased to hear that CMS, JCAHO, and several other collaborating organizations concur that ARBs should no longer be excluded from the CMS and JCAHO quality indicators for heart failure and acute MI. The implementation of the revised heart failure and acute MI measures in 2 phases makes practical sense as described by McClellan and colleagues as well as on the JCAHO Web site (1).

We respectfully disagree with the statement of Drs. Peeters and Tsikouris that the current quality indicators should remain unchanged. A previous meta-analysis by Jong and colleagues (2) showed no statistically significant difference in mortality or heart failure hospitalization rates between ARBs and placebo in patients with heart failure and left ventricular dysfunction. Thus, it was logical that ARB therapy was not part of the JCAHO and CMS quality measures for CHF and acute MI at that time. However, current data show that ARB therapy results in statistically significant reductions in mortality

and heart failure hospitalizations for patients with heart failure and left ventricular dysfunction. Regardless of whether ARBs are considered to be first- or second-line agents to ACE inhibitors, ARBs should be included as part of the heart failure and acute MI quality indicators because they improve clinical outcomes.

We agree with Drs. Peeters and Tsikouris, Mr. Regier, and Mr. Jensen that the efficacy of ACE inhibitors and ARBs may depend on their relative dosing. We did not perform separate analyses based on dosing, however, because the target doses for the ARBs in our study varied widely and we are not aware of standardized criteria for the interconversion of ARB doses.

Finally, we agree with Mr. Regier and Mr. Jensen that in our Table, the doses of valsartan and captopril in the VALIANT study were reported as the target doses from the initial hospitalization but should have been the target doses on 3-month follow-up, which were twice as high.

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CLINICAL OBSERVATION

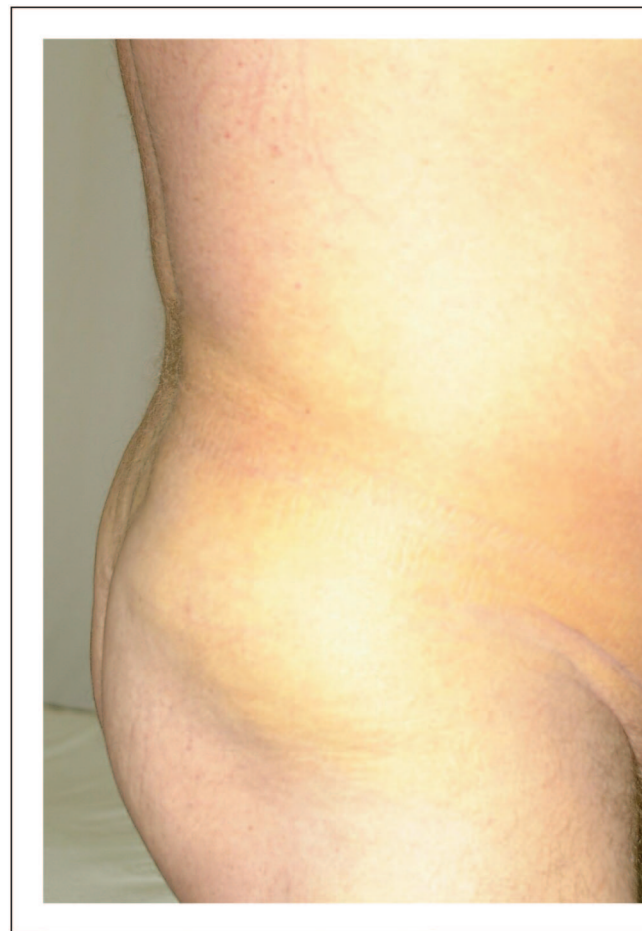
Demarcated Truncal Jaundice: A Sign of Retroperitoneal Bile Leakage

TO THE EDITOR: *Background:* The usual treatment for abdominal collection of bile is percutaneous drainage followed by endobiliary stenting for persistent leaks (1). Delayed drainage can have severe consequences (1). Retroperitoneal bile leaks may behave differently and require different care.

Case Reports: A 43-year-old man was referred with abdominal pain and jaundice 4 days after cholecystectomy. The surgeon had difficulty dissecting the cystic duct, which retracted into the peritoneal fold when it was clipped and divided. A tube placed at the surgical site drained small quantities of serous fluid, but not bile. Skin discoloration was limited to the flanks and groin bilaterally, more marked on the right side than the left. The color of the sclera and the rest of the body, as well as the serum bilirubin level, were normal. Endoscopic retrograde cholangiography demonstrated a cystic duct bile leak. Sphincterotomy was performed, and the discoloration resolved in 4 days.

The second patient, a 59-year-old man, was transferred 5 days after laparoscopic cholecystectomy because of jaundice and a swollen

Figure 1. Demarcation of bile staining in the flank and thigh after laparoscopic cholecystectomy, correlating with the lateral and lower insertions of the fascia of Scarpa.



penis. Jaundiced discoloration and edema of the torso, perineum, and upper thighs contrasted with the sclera, face, and arms, which were normal. A horizontal border in the upper chest and upper thigh

Figure 2. Demarcation of truncal bile staining after laparoscopic cholecystectomy.



The upper limit correlates with the horizontal superior attachment of the fascia of Scarpa.

demarcated the affected area (Figures 1 and 2). Helical computed tomography revealed retroperitoneal fluid that tracked below the fascia of Scarpa to the lower abdominal wall from behind the liver (Figure 3). Endoscopic retrograde cholangiography demonstrated a leak from the cystic stump, and sphincterotomy was performed. Again, no evidence of local inflammation was seen in the areas of staining, which resolved 3 days later.

Discussion: In these patients, “jaundice” was due to bile leakage from the cystic duct within the peritoneal fold of the hepatoduodenal ligament. Tracking along retroperitoneal planes, bile stained tissue deep to the fascia of Scarpa, the membranous layer of the superficial fascia, which limited the area of discoloration by its attachments to the clavipectoral fascia, the lumbar fascia, and the fascia lata of the thigh. The perineal fascia permitted staining of the perineum. This same area is affected by urine extravasation following traumatic disruption of the bulbous urethra.

Leakage of bile from the common bile duct into the retroperitoneal space has been reported before (2). Retroperitoneal perforation of the duodenum may cause bile staining of the scrotum (3). In the 19th century, George Henry Fox is reputed to have noted bruising of the groin with hemorrhagic pancreatitis (4). In 1918, Cullen described periumbilical ecchymosis as a sign of hemorrhage from an ectopic pregnancy (5). Later, it was associated with hemorrhagic pancreatitis. In 1920, Grey Turner described bluish discoloration of the flanks as a sign of hemorrhagic pancreatitis (6). These cutaneous manifestations of retroperitoneal bleeding all lie within the region of truncal jaundice observed in our patients. To our knowledge, the anatomic role of the fascia of Scarpa in these clinical signs has not previously been discussed.

The characteristic feature of the clinical sign described here is the demarcation between jaundiced and unaffected areas of the body. The flanks and the genitalia are stained more than would be expected by examination of the sclera or estimation of bilirubin level. Superiorly, a horizontal line about 3 cm below the clavicles, corresponding to the insertion of the fascia of Scarpa into the clavipectoral fascia, allows an easy comparison between the jaundiced trunk and unaffected adjacent areas, such as the neck, shoulder, and arm. Similarly, a line 3 cm below the groin skin crease corresponds to the insertion of the fascia of Scarpa into the fascia lata of the thigh. In former times, such a sign might have been called *icterus marginatus*.

Conclusion: Bile staining of the tissues in the body wall does not appear to have a detrimental local effect. After laparoscopic cholecystectomy, the most likely source of such bile staining is a leak from the biliary tree within the peritoneal fold of the hepatoduodenal ligament. The significance of this diagnosis is that intraperitoneal drainage may not evacuate the bile collection. In contrast to intraperitoneal collections, the best initial approach to retroperitoneal bile leaks may be endobiliary drainage.

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Figure 3. Helical computed tomogram of the abdomen showing edema below the fascia of Scarpa on the right side of the abdomen in a patient with retroperitoneal bile leakage after laparoscopic cholecystectomy.



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GENERAL COMMENTARY

The International Campaign to Revitalise Academic Medicine

TO THE EDITOR: Academic medicine has been in decline over recent years and is facing a crisis in recruitment. In response to this trend, a working party was appointed to coordinate the International Campaign to Revitalise Academic Medicine (1). More than 40 international medical journals, including *BMJ* and *The Lancet*, and a number of prominent organizations are supporting this campaign (2). The campaign aims to consult all stakeholders and provide a truly international response to the challenges and opportunities facing academic medicine.

Teaching is central to academic medicine, and those who work in this field have traditionally been the educators of tomorrow’s doctors. Students are significant stakeholders in academic medicine, so student involvement in this campaign is crucial. Consequently, a student advisory group to the International Campaign to Revitalise

Academic Medicine was established and an initial meeting was held in October 2004 at the British Medical Association.

The aim of the student advisory group is to respond to questions posed by the working party with a truly global student voice and to proffer opinions and themes that the working party may not have considered. Central to this is the need to construct an international network of students willing to canvas their peers about issues pertaining to academic medicine.

We are appealing directly to students and to doctors who are in a position to encourage any students who may be interested in becoming regional representatives. Those in either of these groups should contact us. We wish to provide a response from students internationally, not just from the western hemisphere. We cannot do this without help and are asking for assistance to contact students who are interested in playing an active role in the campaign. Any interested parties should e-mail us at SAG_ICRAM@yahoo.co.uk.

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CORRECTION

Correction: Angiotensin-Receptor Blockers in Chronic Heart Failure and High-Risk Acute Myocardial Infarction

In a meta-analysis on angiotensin-receptor blockers in chronic heart failure and high-risk acute myocardial infarction (1), the Table contained errors. The doses of valsartan and captopril in the VALsartan In Acute myocardial infarction (VALIANT) study (2) were reported as the target doses from the initial hospitalization but should have been the target doses on 3-month follow-up, which were twice as high.

In the column titled “ARBs and Target Doses,” the values for the VALIANT study should have read as follows: 1) valsartan, 160 mg twice daily; 2) valsartan, 80 mg twice daily, plus captopril, 50 mg 3 times daily. In the column titled “Controls,” the value for the VALIANT study should have been captopril, 50 mg 3 times daily. In addition, the second half of the third sentence under the heading “High-Risk Acute MI” should have read as follows: “while the VALIANT study demonstrated a non-statistically significant advantage with ACE [angiotensin-converting enzyme] inhibitors for all-cause mortality (odds ratio, 1.03 [CI, 0.93 to 1.13]) and a non-statistically significant advantage with ARBs [angiotensin-receptor blockers] for hospitalizations for heart failure or acute MI (odds ratio, 0.97 [CI, 0.87 to 1.07]).”

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