The "Shaken-Baby Syndrome"

To the Editor: Duhaime et al. (June 18 issue)[1] skirt the fact that there is no objective evidence that the entity called the "shaken-baby syndrome" exists. This is not just my opinion as a forensic pathologist with 30 years of experience but also the opinion of many of my colleagues, and if one reads the article by Duhaime et al. carefully, it is their opinion by implication. In the second paragraph, they note that "it is the sudden deceleration associated with the forceful striking of the head against a surface that is responsible for most, if not all, severe, inflicted brain injuries." That it is widely recognized that the head injuries in this syndrome are due to impact and not shaking is reflected by the use of the term "shaking–impact syndrome."

If one has proof of impact, why hypothesize that the child was shaken? There are no lesions to prove the child was shaken. You cannot base such a judgment on self-serving statements by the person who inflicted the injuries. Adding the word "impact" to the term "shaken-baby syndrome" does not prove the existence of the entity or justify the retention of this term. Let us simply drop both the term and the concept of the shaken baby and face the fact that the injuries are due to the impact of being slammed, swung, or thrown against a hard surface, such as a wall, the floor, or furniture.

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1. Duhaime A-C, Christian CW, Rorke LB, Zimmerman RA. Nonaccidental head injury in infants — the "shaken-baby syndrome." N Engl J Med 1998;338:1822-9.

To the Editor: The presenting symptoms of the shaken-baby syndrome, as described by Duhaime et al., bear a remarkable resemblance to another problem of infancy, known as an apparent life-threatening event.[1] This term is used in the case of an infant, usually less than 12 months old, who is found in an unresponsive, apneic, cyanotic, or limp state but who recovers spontaneously or is successfully resuscitated, a situation that has led to the use of the term "near-miss sudden infant death syndrome."[2] Because of the similarity in the presentations of these two entities, and because the cause of an apparent life-threatening event remains unknown in many cases,[1] we began considering the possibility that some apparent life-threatening events of unknown cause may actually be occult cases of the shaken-baby syndrome.

We began performing funduscopic examinations of dilated eyes to look for retinal hemorrhages in infants admitted to our hospital after an apparent life-threatening event of unknown cause. Retinal hemorrhage is one of the key findings associated with the shaken-baby syndrome. In 1995, approximately 75 infants were admitted to the Children's Hospital at Westchester Medical Center for evaluation of an apparent life-threatening event, and 5 infants under one year of age were discharged with a final diagnosis of the shaken-baby syndrome. The initial history and physical examination on admission revealed no apparent cause, but examination of dilated eyes in four of the infants revealed retinal hemorrhages. Subsequent imaging studies of the head demonstrated subdural hemorrhages in all four cases. In the fifth patient, a computed tomographic scan of the head, obtained because of focal seizures, revealed subdural hemorrhages. In this patient, the retinal examination showed no abnormalities, but the skeletal survey showed evidence of an unexplained, healing femoral fracture, a finding that strongly suggested the diagnosis of child abuse.

Most clinicians do not usually consider the shaken-baby syndrome in the differential diagnosis when evaluating an infant who appears to be well for a recent apparent life-threatening event. If there is a link between these two entities, physicians will need to consider the shaken-baby syndrome in evaluating infants with an apparent life-threatening event of unknown cause.

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1. Kahn A, Montauk L, Blum D. Diagnostic categories in infants referred for an acute event suggesting near-miss SIDS. Eur J Pediatr 1987;146:458-60.
2. Dunne K, Matthews T. Near-miss sudden infant death syndrome: clinical findings and management. Pediatrics 1987;79:889-93.

The authors reply:

To the Editor: Dr. Di Maio makes an important point, with which we agree: the evidence of an impact is clearly more objectively verifiable than the evidence of shaking, which is based largely on the clinical history. As Dr. Di Maio notes, many children with this syndrome have histories and findings consistent with an impact alone. Although the terminology and mechanisms may be debated, the entity that has been known as the shaken-baby syndrome clearly exists as a useful diagnostic paradigm. Many clinicians, pathologists, and child advocates are convinced that shaking is a part of this syndrome because of their collective experience with histories and confessions in which shaking was described. The possible causative relation between shaking and findings that include retinal hemorrhages, skeletal injuries, and trauma to the cervical spinal cord resulting in respiratory compromise require further research.

Ideally, the terminology for inflicted injuries would be independent of the purported mechanisms, since they remain controversial and inherently difficult to study. Our use of the term "shaking–impact syndrome" is meant to be inclusive of impact-related deceleration until more suitable terminology evolves and our understanding of mechanisms improves.

Dr. Altman and colleagues point out an association between apparent life-threatening events and inflicted head injury. We agree that some infants with life-threatening events are unidentified victims of child abuse. Early detection of the shaking–impact syndrome is improved by routine ophthalmologic examination as well as careful attention when there is blood in the cerebrospinal fluid. The possibility of child abuse needs to be included in the differential diagnosis for all infants with altered mental

status, subtle neurologic signs, and unexplained apnea or vomiting.

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Treatment of Head and Neck Cancer

To the Editor: Brizel et al. (June 18 issue)[1] conclude that hyperfractionated irradiation with concurrent chemotherapy "is more efficacious and not more toxic than hyperfractionated irradiation alone." At three years, the estimated rate of overall survival was 55 percent in the combined-therapy group and 34 percent in the hyperfractionation group ($P=0.07$). This difference is not statistically significant.

Feeding tubes were required in 44 of 56 patients (79 percent) in the combined-treatment group and 29 of 60 patients (48 percent) in the hyperfractionation group. Soft-tissue necrosis occurred in 11 patients (20 percent) in the combined-treatment group and 7 patients (12 percent) in the hyperfractionation group. Sepsis developed in 14 patients (25 percent) in the combined-treatment group (including 1 who died) and 4 patients (6.7 percent) in the hyperfractionation group. How can the authors conclude that combined treatment is "not more toxic than hyperfractionated irradiation therapy alone"?

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1. Brizel DM, Albers M, Fisher SR, et al. Hyperfractionated irradiation with or without concurrent chemotherapy for locally advanced head and neck cancer. N Engl J Med 1998;338:1798-804.

To the Editor: Brizel et al. conclude that "combined treatment [chemotherapy and irradiation] for advanced head and neck cancer is more efficacious and not more toxic than hyperfractionated irradiation alone." The data presented, however, do not provide very strong support for this conclusion.

The same number of patients in each group (six) had distant metastases. The contention that metastasis might have been prevented if five patients in the combined-treatment group had received additional chemotherapy is unsupported. Likewise, the proportion of patients with a local first recurrence of disease (at the primary site) did not differ significantly between the two groups: 35 percent in the hyperfractionation group and 29 percent in the combined-treatment group ($P=0.55$, by a two-sided Fisher's exact test). The greatest difference in the rates of treatment failure involved recurrences in regional nodes (in 15 of the 60 patients in the hyperfractionation group vs. 0 of 56 in the combined-treatment group).

The authors acknowledge that the two groups differed with respect to the nodal stage at diagnosis. According to our calculation, the P value for this difference (in a two-by-two comparison with a two-sided Fisher's exact test) is 0.09, not 0.31. The difference in nodal stage could explain the worse survival in the hyperfractionation group, a difference of borderline significance. Since nodal dissection was not performed in all the patients, conclusions about differences in regional control and survival are confounded. Differences in overall rates of recurrence at the primary site (with or without nodal recurrence) were not reported but would be of interest in interpreting the only statistically significant finding in the study, the difference in locoregional control. In addition, knowledge of the rates of salvage surgery and ultimate preservation of organ function in patients initially enrolled for the purpose of preserving organ function (nearly half the patients) is important in comparing the groups.

There was greater toxicity in the combined-treatment group, with a higher incidence of sepsis (14 percent, as compared with 4 percent in the hyperfractionation group; $P=0.15$), which caused the death of one patient, and an increased need for a feeding tube (44 percent vs. 29 percent, $P=0.08$). The increased toxicity was seen despite a 15 percent reduction in the intensity of the radiation dose in the combined-treatment group. The evidence of improved survival and possibly improved local control appears to be no stronger than the evidence of increased toxicity with combined treatment.

Improvements in local control and survival that have been demonstrated with combined treatment for lung, gastrointestinal, and breast cancers; lymphoma; pediatric soft-tissue sarcomas; and nasopharyngeal carcinoma required larger studies with less heterogeneous patient populations. The hope is that incremental improvements in radiotherapy, expanding chemotherapeutic options, and a better understanding of how to integrate these approaches, thanks to studies such as that reported by Brizel et al., will lead to more convincing evidence of the benefit of chemotherapy for selected patients with head and neck cancer.

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To the Editor: I do not believe that Dr. Brizel and colleagues are entitled to draw the conclusions they do from the evidence presented. As is so often the case with prospective, randomized studies of patients with advanced head and neck cancer, the multiplicity of primary sites and stages makes comparisons difficult, and much larger groups of patients are required than the 122 who underwent randomization in their study, only 116 of whom could be included in the analysis. In the current nationwide collaborative trial in the United Kingdom, for example, which has strong support from London, Edinburgh, Glasgow, Manchester, and Birmingham — all the major urban centers — close to 1000 patients have been recruited, a number barely sufficient for a comparison of chemotherapy with no chemotherapy.

In the study by Brizel et al., the patients in the two groups were not well matched. Most authorities on head and neck cancer agree that the most important prognostic feature is the nodal status in the neck, yet in the more favorable N0–N1 category, there were 23 patients in the