

## **BAG RECALL: BIS or Anesthesia Gas to Reduce Explicit reCALL**

The incidence of anesthesia awareness (AA) is 0.1-0.2% and may result in post traumatic stress disorders. For some patients, owing to illness, medications, substance misuse or surgery, the risk approaches 1%. The B-AWARE Study suggested that the bispectral index (BIS) monitor, which reportedly reflects anesthetic depth, may decrease the incidence of AA in higher risk patients by 82%. The American Society of Anesthesiologists has published a practice advisory on AA, which does not recommend the routine use of cerebral function monitors. We propose to test the hypothesis that an anesthetic protocol based on BIS decreases the incidence of AA among higher risk patients compared with an anesthetic protocol based on the end-tidal anesthetic gas (ETAG) concentration. We have completed a randomized, single-blinded prospective feasibility study (The B-Unaware Trial) which enrolled 2000 patients. Four patients (0.21%; 95% CI=0.06% to 0.57%) had definite AA, of whom two were in the BIS group and two in the ETAG group. Nine patients (0.46%; 95% CI=0.22% to 0.91%) had definite or possible AA, of whom six were in the BIS group and three in the ETAG group. The BAG RECALL study will be a dual center, prospective, single-blinded, randomized study enrolling 6000 patients at higher risk for AA. The BAG RECALL study is adequately powered and rigorously designed to answer with a reasonable degree of scientific probability whether BIS guidance results in clinically relevant reduction in anesthesia awareness among higher risk patients undergoing general anesthesia.