

ASMBS POSITION STATEMENT ON EMERGING ENDOSURGICAL INTERVENTIONS FOR TREATMENT OF OBESITY

The American Society for Metabolic and Bariatric Surgery Emerging Technologies and Clinical Issues Committees of the ASMBS

Approved by the ASMBS Executive Council January 2009

The following position statement is issued by the American Society for Metabolic and Bariatric Surgery in response to numerous inquiries made to the Society by patients, physicians, society members, hospitals, health insurance payers, the media, and others, regarding emerging endosurgical interventions for treatment of obesity. In this statement, the ASMBS establishes its position on the appropriate steps to be taken before acceptance of new technologies for the treatment of obesity which are based upon current knowledge, careful consideration of experts, and published peer-reviewed scientific evidence available at this time. The intent of issuing such a statement is to provide objective information about the process which should be followed in this exciting time of development for endosurgical interventions. The statement is not intended as, and should not be construed as, stating or establishing a local, regional or national standard of care. The statement will be revised in the future as additional evidence becomes available.

Emerging technologies present an opportunity for us to improve patient outcomes and are essential to the evolution of the practice of medicine. Modern day bariatric surgical interventions have developed from a rich history of pioneering surgical innovation, defined recently as ‘a new procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient’ [1]. Decades of outcomes research have led to published standards regarding surgical risk, weight loss outcomes, and durability of various procedures in longterm follow-up. The result has been the progressive acceptance of bariatric surgery as a mainstream intervention for treatment of the morbidly obese patient. Current ethical standards indicate that innovation requires appropriate oversight “to assess the relative merits and potential adverse consequences” [1-4]

There are currently a number of endoluminal innovations and novel devices and technologies in various stages of development or application to the elective treatment of obesity, including revisional interventions. Theoretical goals of these therapies include decreasing the invasiveness, risk, and barriers to acceptance of effective treatment for obesity, but these outcomes can not be assumed and must be proven. Therefore, use of novel technologies should be limited to clinical trials done in accordance with ethical guidelines of the ASMBS and designed to evaluate the risk and efficacy of the intervention. Results of appropriate trials should include generation of data for risk-benefit analysis, assessments of disability, durability, and the resource utilization associated with the intervention. An intervention undergoing evaluation

should not be judged favorably if risk to benefit ratio is increased over the spectrum of currently accepted surgical procedures [5]. Dramatic reduction in risk may allow for acceptance of interventions which do not provide traditional durable benefits comparable to currently accepted bariatric procedures [6].

Unfortunately, it has become clear that clinical trials can and have been manipulated by for profit medical device companies and that this influence on clinical trial results can misrepresent the outcomes of the clinical trial. It is therefore essential to ensure the integrity of clinical trials by recommending the following actions of physicians involved in clinical trials, as recommended by JAMA.[7] and supported in full by the ASMBS in this Position Statement, i.e. "For-profit companies that sponsor biomedical research studies should not be solely or primarily involved in collecting and monitoring of data, in conducting the data analysis, and in preparing the manuscript reporting study results. These responsibilities should primarily or solely be performed by academic investigators who are not employed by the company sponsoring the research". Furthermore the society supports the registration of all clinical research trials and mandatory reporting of outcomes whether favorable or not.

If evidence supports use of a new intervention, several other factors need to be considered before clinical application outside the controlled environment of a clinical trial. As weight loss interventions are believed to result in better outcomes when treatment is part of a comprehensive treatment program, clinical use of a new intervention should be practiced in the setting of a multidisciplinary treatment team. Nutritional support, experienced nursing care, behavioral medicine specialists and physicians experienced in the management of bariatric patients and their comorbidities are essential components of such a program. Patients must be educated with honest and informed consent about the procedures to be used including any lack of knowledge relating to duration of effectiveness. Training and skill acquisition with the techniques and technology are mandatory before clinical application is undertaken and must include didactic as well as hands-on education.

In addition the ability or availability of physicians and surgeons willing and able to manage potential complications in morbidly obese patients is advised.

These guidelines are not intended to thwart innovation but rather to support careful evaluation, develop evidence of effectiveness of new interventions, and to protect patients. These guidelines are also not meant to dictate appropriateness of a given technology within a specific clinical situation, but highlight the importance of adequately informing the patient prior to intervention and emphasize the need to study the outcomes of novel therapies.

Emerging Endosurgical Interventions for Treatment of Obesity Position Statement and Standard of Care

This Position Statement is not intended to provide inflexible rules or requirements of practice and is not intended, nor should it be used, to state or establish a local, regional, or national legal standard of care. Ultimately, there are various appropriate treatment

modalities for each patient, and the surgeon must use their judgment in selecting from among the different feasible treatment options.

The American Society for Metabolic and Bariatric Surgery cautions against the use of this position statement in litigation in which the clinical decisions of a physician are called into question. The ultimate judgment regarding appropriateness of any specific procedure or course of action must be made by the physician in light of all the circumstances presented. Thus, an approach that differs from the position statement, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious physician may responsibly adopt a course of action different from that set forth in the position statement when, in the reasonable judgment of the physician, such course of action is indicated by the condition of the patient, limitations on available resources or advances in knowledge or technology. All that should be expected is that the physician will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient, in order to deliver effective and safe medical care. The sole purpose of this position statement is to assist practitioners in achieving this objective.

References:

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