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Tumescent Liposuction

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Executive Summary

Tumescent liposuction, also known as suction-assisted lipectomy or lipoplasty, is a cosmetic surgical procedure that removes unwanted fat deposits under the skin. Liposuction is the most common elective cosmetic procedure performed in the United States, with an estimated 450,000 procedures performed in 2000.[1,2] Tumescent liposuction infuses a balanced salt solution, including dilute epinephrine, to thicken the subcutaneous fat layer, allow for greater volumes of fat to be aspirated, and decrease blood loss to an amount as low as 1 percent. [3,4] Lidocaine may be added to the solution to provide local anesthesia during the procedure. Liposuction is a nontrivial procedure that may potentially involve a painful recovery, serious complications, and death.

Controversy exists around the safety of liposuction. Since liposuction was introduced in the U.S. in 1982, serious complications and deaths have been reported in the literature and popular press. A census survey of aesthetic plastic surgeons for the period 1994 to mid-1998 found the death rate to be 1 in 5224 (19 in 100,000) for liposuction performed either alone or in combination with other procedures. [5] Of 93 liposuction deaths in 496,245 procedures, 23% were attributed to thromboembolism, 15% to abdominal or visceral perforations and 10% were from anesthesia, sedation or medication problems. Hughes, in a census survey of aesthetic plastic surgeons conducted for the period of September 1998 through August 2000, found that the estimated overall risk of death from liposuction was 8.4 in 100,000. [6] The author reported mortality rates in three categories of liposuction procedures. When liposuction was performed alone (66% of procedures) the mortality rate was 1 in 47,415. When liposuction was performed with other procedures excluding abdominoplasty (20% of procedures), the mortality rate was 1 in 7314. When liposuction was performed with abdominoplasty, with or without other procedures (14% of procedures), the mortality rate was 1 in 3281. The author attributed the reduction in mortality to modifications made in physician practices resulting from education through safety guidelines.[7] However, these mortality ratios stand in contrast to a 1 in 100,000 mortality rate for other elective surgical procedures. The true incidence rate is not known since reporting of adverse events related to liposuction is not mandatory.

Many of the studies reviewed were small in size. Liposuction has not been systematically studied, either alone or when used concomitantly with other procedures. Most of the research failed to indicate clear-cut objectives, and objectives of most of the studies were subjective.

Issues surrounding the safety of liposuction are: method of sedation (general, regional, local), lidocaine toxicity, fluid balance, physician qualifications, and where the procedure is performed.

In a review of deaths in New York occurring after liposuction, Rao et al. concluded that tumescent liposuction has the potential to be a fatal procedure, in part because of lidocaine toxicity or lidocaine-related drug interactions.[8] Klein reported no blood transfusions, adverse drug reactions, infections, or hypovolemia in 112 patients undergoing large volume (>1500 mL) liposuction.[4] Subcutaneous infusion of high volumes of tumescent solution, as well as

additional fluids administered intravenously, can potentially cause complications of hypervolemia and pulmonary edema. Trott et al., in a fluid management study of 53 liposuction patients, found no significant complications and developed suggested guidelines for managing fluids.[9] While any physician is allowed to perform liposuction, physicians who are board-certified by an accredited organization have the qualifications and experience to do the procedure. There are many non-accredited specialty boards that give certifications and make selecting a physician confusing for the public. With the movement of more procedures away from hospital settings, reporting requirements for adverse events do not apply.

Conclusions
Liposuction is generally safe, provided patients are carefully selected, the facility is properly equipped and the physician has accredited training with special training and experience in liposuction.

Sound clinical judgment based on a clear understanding of the physiologic events surrounding subcutaneous infusion of fluids and anesthetics is crucial for patient safety. Local, regional, and general anesthesia and combinations thereof are acceptable methods of sedation for liposuction.

Controversy exists over the role of lidocaine in the tumescent solution and its potential for toxicity.

Liposuction can be safely performed in hospitals, surgical centers and physician offices depending upon the number of surgical incisions and volume removed.

The liposuction-related death rate is estimated to be 8.4 in 100,000, which is higher than the incidence rate of other elective procedures (1 in 100,000). Because mandatory reporting of liposuction-related complications or deaths does not exist, the actual incidence of these events is unknown.

Deaths and disfigurement due to the cosmetic surgical procedure of liposuction should be a matter for serious public concern.

Recommendations
Patients should carefully choose the physician and facility where liposuction is to be performed. They should inquire as to qualifications and experience of the entire surgical team, including the anesthesia staff. They should assure that the facility has adequate technology to care for them during the procedure and in the event of a complication.

Patients should determine what contingency plan the facility has in the event of an emergency. It should include a fully-supplied crash cart, staff trained in resuscitation, and a provision for patient transfer to provide acute care.

Reassessment of drug absorption and interactions, fluid management, prothrombogenic factors and liposuction volume should be encouraged.

Outcomes data should be gathered by the Department of Health that includes mandatory reporting of 30-day major morbidity (e.g. myocardial infarction, migration of venous thrombi and pulmonary emboli) and mortality.

Background

Liposuction, also known as lipoplasty or suction-assisted lipectomy, is a cosmetic surgical procedure that removes unwanted fat deposits under the skin. Liposuction was first performed as a method of fat removal in Italy in the mid-1970s. The modern technique of liposuction was developed in the late 1970s by French doctors Gerald Illouz and Pierre Fournier, and was introduced to the U.S. in 1983.[10]

Liposuction is the most common elective cosmetic procedure performed in the United States. In 2000, an estimated 450,000 liposuction procedures were performed; the American Society for Plastic Surgery reported roughly 350,000 procedures performed with an additional 100,000 operations performed by dermatologists.[1,2] Liposuction is most commonly performed on the outer thighs and abdomen in women and the flanks in men. However, liposuction can also remove unwanted fat from the hips, buttocks, knees, upper arms, chin, cheeks, neck and other areas. Liposuction is a nontrivial surgical procedure that may involve a painful recovery and serious complications.

Although liposuction is usually performed for cosmetic reasons as a elective procedure, it can be used for the following medical indications: single or multiple lipoma, angiolipoma, benign symmetrical lipomatosis, or Madelung's disease, Dercum's disease, gynecomastia, pseudogynecomastia, or insulin-induced lipohypertrophy, axillary bromhidrosis, axillary hyperhidrosis, aspirate hematoma, lymphedema, particularly following breast cancer, and stomal disorder.[11]

Procedure

Liposuction involves inserting a narrow tube (cannula) under the skin through small incisions and manipulating the cannula to break up and aspirate fat cells. The procedure injures local tissues, leading to bruising, swelling and blood loss. Early techniques were characterized by frequent morbidity, with patients losing substantial amounts of blood. However, since liposuction was first introduced in the 1970's, newer techniques have decreased adverse outcomes.

Tumescent liposuction was first described by Klein in 1987.[12] The tumescent technique was a progression from the "dry" technique in which no fluids were injected subcutaneously and often resulted in blood losses that required transfusions. Tumescent liposuction infuses a balanced salt solution, including dilute epinephrine, to thicken the subcutaneous fat layer, allow for greater volumes of fat to be aspirated, and decrease blood loss. Lidocaine may be added to the solution to provide local anesthesia during the procedure.[13,14]

Epinephrine causes vasoconstriction which is believed to decrease bleeding during and after liposuction, prolong the anesthetic effect, and slow the systemic absorption of lidocaine, allowing larger doses to be administered safely.[4,13]The addition of sodium bicarbonate neutralizes the pH of the solution, which decreases the burning sensation upon infiltration, while increasing lipid solubility and systemic absorption of lidocaine, and triamcinolone decreases postoperative soreness.[4] When lidocaine is added to the tumescent solution, it is believed by its proponents to produce less postoperative pain and a faster recovery time.[15]

After the removal of the aspirate, the incision sites are left open to drain and compression garments are worn for a number of weeks after surgery in order to lessen the swelling and assist in body shaping. The addition of a local anesthetic and epinephrine to the infused solution provides 10-14 hours of postoperative pain relief. It can take three to four months for the swelling to be completely resolved.[16] Most patients do not need analgesics other than acetaminophen (Tylenol). Treatment with oral antibiotics begins the day before the procedure and continues for approximately five days.

Before the advent of tumescent techniques, perhaps 20-45 percent\plain\f4\fs22 [16] of the total volume extracted during liposuction consisted of blood. As tumescent techniques were refined, blood loss was further reduced from 15-30 percent[17] of aspirate containing blood to as low as 1 percent. [3,4] As a result, tumescent liposuction reduces complications such as shock and anemia secondary to hemodilution and blood loss, and allows for the removal of much more fat during a single procedure.

Ultrasound-assisted liposuction (UAL): Ultrasound has been utilized with tumescent liposuction in an attempt to cause fat cells to rupture and release their contents, which are then removed via suction. Ultrasound can be utilized either internally or externally. Several authors have advocated the use of ultrasound as an augmentation to tumescent liposuction, believing it may lessen postoperative swelling and bruising. Cooter et al. found the evidence base for UAL's safety and efficacy to be inadequate, and stated it is not a replacement for traditional liposuction but may complement it by allowing contouring in areas not otherwise possible.[18] The Federal Food and Drug Administration (FDA) expressed concern about internal ultrasound because the special cannulas are not approved for liposuction, and there is potential for severe burns if the wand is not moved constantly. [14] There are reports of a higher incidence of seromas, skin necrosis, end hits (thermal damage caused when the ultrasonic probe contacts non-adipose tissue), and larger incision sites for the cannulas with internal ultrasound.[19] Blood loss using internal ultrasound was found to be comparable to suction lipoplasty - approximately 1 percent of the total aspirate.[3]

Lawrence and Cox conducted a double-blind, placebo-controlled trial of external ultrasound-assisted tumescent liposuction in 19 patients.[20] The patients received active ultrasound (20-30 W) on one side and sham ultrasound (2-3 W) on the other. In 14/19 patients, there was either no difference between the control and treated sides or better response in the non-treated side in terms of fat removal and resistance to cannula advancement (P=0.0096). The authors concluded that there was no objective or subjective advantage to ultrasound augmentation of tumescent liposuction. This study was very small in sample size.

The FDA points out that the short-term effects i.e., free fat entering the blood stream and long-term ultrasonic effects on tissues are not known.

Findings

Many of the studies reviewed used samples of patients that were too small to draw inferences about the safety of tumescent liposuction, either alone or in conjunction with other procedures. Most of the research failed to indicate clear-cut objectives, and the outcomes of most of the studies were subjective in nature. None of the authors used a scientific basis to arrive at their conclusion about the efficacy of tumescent liposuction.

Klein reported results from 112 patients (mean female wt 68.6 kg, mean male wt 93.1 kg) who were having >1500 mL of fat liposuctioned.[4] Mean volume of tumescent solution was 4608 ml, mean volume of total aspirate was 2657 mL, of which the mean volume of fat was 1945 mL. Mean volume of whole blood removed by liposuction was 9.5 mL/L of fat. There was no evidence of intravascular volume depletion in any patient. No patient received blood transfusion or intravenous or IM analgesia for the procedure. The author reports no adverse drug reactions, infections, seromas, hematomas or hypovolemia. The study does not mention the incidence of minor complications and concludes that large-volume (<1500 mL) liposuction can be performed by the tumescent approach. However, neither plasma lidocaine nor hemoglobin concentrations were reported.

Bank and Perez reported a case series of tumescent liposuction in 58 patients over age 40 (mean age 55).[21] The average fat extracted from abdominal liposuction was 1725 mL, with an average lidocaine dose of 36 mg/kg. Six months after surgery, these patients (n=30) averaged a 5-lb loss of weight and a 3-inch decrease in waistline. In neck liposuction, the average lidocaine dose was 4 mg/kg, with an average of 75 mL of fat extracted. These patients (n=20) had a decreased circumference of 1.3 inches. In arm liposuction (n=8), average fat removed was 525 mL, with an average lidocaine dose of 16 mg/kg, and a mean decrease in circumference of \'bd inch. Complications included seromas (2), both in patients that had abdominal liposuction. The authors conclude that patients over 40 receiving tumescent liposuction can achieve good to excellent results without the need for abdominoplasty. However, observations of efficacy were made subjectively, with a lack of objective validation.

Plasma lidocaine or hemoglobin concentrations were not reported. The authors did not report complications secondary to lidocaine.

Rao et al., in a review of autopsy reports in the Medical Examiners Office in New York City, reported five deaths that occurred after tumescent liposuction.[8] Background data was only available for four of the patients, and are summarized in Appendix II. In this study, the authors reviewed all autopsy reports from 1993 through 1996 and death-notification records from 1993 to March 1998, at the New York City medical examiner's office (n=48,527). They also questioned the city medical examiners about any deaths possibly related to liposuction that were under investigation. The medical records of patients whose death was related to the procedure were reviewed for information about the liposuction procedure itself, the amount of lidocaine administered during the procedure, premorbid conditions and medication used. Five of the 1,001 deaths certified by the medical examiner's office as resulting from therapeutic complications were related to liposuction. In four cases, the procedure was performed by a plastic surgeon and in one case, by a general surgeon. In all cases, an anesthesiologist was in attendance. Family members of four of the patients consented to a published description of the cases.

Rao reported deaths occurred in a 33-year-old man and in three women who were 33, 40 and 54 years of age. In two cases, hypotension and bradycardia were followed by asystole during the procedure. A third patient had been discharged from the hospital for two hours when she had a syncopal episode and was found to be in ventricular fibrillation. This patient was resuscitated but remained unresponsive and in an anoxic coma. She was pronounced dead three days later. The fourth patient became "lightheaded" 18 hours postoperatively and then became unresponsive. Autopsy findings in this patient included a deep venous thrombosis of the calf with saddle and distal pulmonary emboli. In all cases, resuscitation was attempted. Rao concluded that tumescent liposuction has the potential to be a fatal procedure, in part because of lidocaine toxicity or lidocaine-related drug interactions.

In an evaluation of 124 patients, Fulton et al. determined that the cannulas and sedation used in tumescent liposuction were safe and effective in all cases.[22] However, objective data were not included in their report.

Trott et al. conducted a prospective study of fluid management in 53 patients.[9] Urine output was measured in 36 patients. Twenty-eight patients underwent large volume liposuction, defined in this study as volume of aspirate 4L. Hypotension developed in four patients. All other patients received maintenance fluid postoperatively until oral intake resumed. No significant complications were reported. Ninety-three percent of patients were discharged within 24 hours of surgery. The authors suggested the following guidelines for fluid management based on retrospective review of intra- and postoperative clinical outcomes. For small volume (< 4L aspirated): maintenance fluid + subcutaneous tumescent solution. For large volume (\plain\f6\fs22 \'b3\plain\f4\fs22 4L aspirated): maintenance fluid + subcutaneous tumescent solution + IV crystalloid for aspirate removed above 4L.

Two foreign studies examined the efficacy of large-volume tumescent liposuction. A case series conducted in Mexico by C\'e1rdenas-Camarena et al. reported the results of large-volume tumescent liposuction on 161 patients (mean age 36, mean weight 72 kg) for a mean follow-up of 21 months.[23] Average weight loss was 6 kg and suction amounts ranged from 5 to 22.3 L, with a mean of 8700 mL. The average decrease in hemoglobin and hematocrit was 3.8 g/dl and 12% respectively. Mean surgical time was 2.25 hours. Thirty-two percent of patients presented with complications, including the following: palpable/visible irregularities (20%) seroma (11%), scar hyperpigmentation (5%), cutaneous necrosis (1%). Ninety-two percent of patients reported great satisfaction with the results. Blood transfusions were anticipated and necessary in 28 patients. The authors found that aspirate contained under 10% of blood for the first 6L removed, and the percentage increased in volumes removed above 6L. They concluded that large-volume tumescent liposuction is viable in the achievement of improved body contouring and weight loss. In 1998, C\'e1rdenas-Camarena & Gonzalez reported on large-volume

liposuction performed with abdominoplasty in a sample of 42 women (mean age 40, mean weight 64 kg).[24] Average weight loss was 7 kg and liposuction volumes ranged from 1.6 to 11.2L, with a mean of 4.2L. Tissue extracted from abdominoplasty varied from 400 to 5000 g with an average of 1300 g. Complications reported were: necessity of blood transfusions, asthenia, distal necrosis of flap and seromas. The authors concluded that combining these two surgeries is viable.

Patient Selection Criteria

Tumescent liposuction is usually performed for cosmetic reasons as elective surgery. Since the procedure did not need to be FDA approved, there are no patient selection criteria found in the literature. However, several authors offer suggested guidelines. Medical, physical and psychosocial evaluation of the patient should be done prior to liposuction surgery.[6,25] Liposuction is indicated in patients who have subcutaneous adipose deposits out of proportion to their overall body shape, and weight that falls in the normal range for their height. Patients with poor skin elasticity or persons age 40 and over, may experience less skin retraction after liposuction, with draping of the skin that may require surgical correction following the liposuction.[11] Liposuction is contraindicated in patients with morbid obesity, severe cardiovascular disease, coagulation disorders and during pregnancy.[25,26]

Safety

Substantial controversy exists around the safety of tumescent liposuction. Liposuction has been marketed as a "day at the spa." Patients, in their desire to improve their physical appearance, may overlook the fact that liposuction is surgery, and surgery carries risk, including death.[27]

Since liposuction was introduced in the United States in 1982, serious complications and deaths have been reported in the literature and lay press. The true incidence rate is not known since reporting of liposuction-related adverse events is not mandatory. Issues surrounding the safety of liposuction are: the method of sedation, lidocaine toxicity, fluid balance, physician qualifications, and where the procedure is done. Census surveys and case studies have been conducted to determine morbidity and mortality related to liposuction. Appendix III lists reports of serious complications and deaths related to liposuction.

Several deaths have been reported in patients who received tumescent liposuction. In 1997, 67 deaths related to liposuction, possibly as many as 100, were reported by a malpractice insurance company in California. An accurate number was difficult to discern due to the fact that litigated cases are settled and not formally reported.[28,29] After several reports of deaths in Florida and subsequent legislative hearings, the State of Florida adopted regulations for office-based surgery[30](see Appendix IV).

There is disagreement over the causes of death related to liposuction. In a study of deaths in New York occurring after tumescent liposuction between 1993 and 1998, Rao et al. reported that some of the patients received general anesthesia, some patients may have had defective liver function/s that interfered with the metabolism of lidocaine, and it was theorized that some may have reached potentially toxic plasma levels of lidocaine.[8] Some dermatologists believe that general anesthesia increases the morbidity and mortality risks in tumescent liposuction.[13] In the opinion of some plastic surgeons, eliminating the lidocaine from the infused solution and providing anesthesia by other means reduces the morbidity and mortality risk by removing the potential for lidocaine toxicity while retaining the advantages of this technique.[31] It is also believed that multiple cosmetic procedures performed during the same operation and the removal of large amounts of fatty tissue from several anatomic regions during the same operation increase the risk of serious complications.

A census survey of 1200 aesthetic plastic surgeons was conducted for the period 1994 to mid-

1998.[5] A total of 841 surveys were returned for a response rate of 70 percent. The responses revealed a death rate of 19 in 100,000 (1 in 5224) for liposuction performed alone or in combination with other procedures, greater than the average fatality rate from car accidents (16 in 100,000). The rate contrasts with the 1 in 100,000 mortality rate for other elective surgical procedures. Of 93 liposuction deaths in 496,245 procedures, 23% were attributed to thromboembolism; 15% to abdominal or visceral perforations, and 10% were from anesthesia, sedation or medication problems.

Hughes conducted a census survey of 1432 aesthetic plastic surgeons for the 24-month period covering September 1998 through August 2000.[6] A total of 754 questionnaires were returned for a response rate of 53 percent. The results found that the estimated overall risk of death from liposuction was 8.4 in 100,000. The author reported the mortality rates of 94,159 liposuction procedures by three categories. When liposuction was performed alone (66% of procedures), the mortality rate was 1 in 47,415. When liposuction was performed with other procedures excluding abdominoplasty (20% of procedures), the mortality rate was 1 in 7314. When liposuction was performed with abdominoplasty, with or without other procedures (14% of procedures), the mortality rate was 1 in 3281. The reduced mortality rate is attributed to educational efforts in safety guidelines[7] for liposuction. The survey found that nearly one-third of respondents had modified their practice in the 24-month survey period. The most frequent modification was that liposuction was less likely to be performed in combination with certain other procedures. Other changes made were stricter patient selection, shorter surgery times, and removal of smaller volumes of fat. Among the respondents operating in office-based facilities, 65 percent stated that their facility was state-licensed, Medicare-certified or accredited by a national or state-recognized accrediting organization.

Hanke and colleagues sent a survey to 1778 members of the American Society for Dermatologic Surgery in 1994 and found no serious complications or deaths in over 15,000 liposuction patients.[13] However, the survey response rate was less than 4 percent.

In an editorial, the medical director of a malpractice insurance company stated that liposuction comprised 17% of all plastic surgery claims in 1997. By 1999, however, liposuction accounted for only 1% of plastic surgery claims.[32]

Method of Sedation

The method of sedation used in tumescent liposuction varies depending upon the physician's technique, number of surgical sites involved, volume to be aspirated, facility where surgery is performed, and to some degree, patient preference. The types of anesthesia used in liposuction are local, regional, general, or combinations of general and local or regional.

The advantages of using only local and regional anesthesia are that time intervals are shorter to oral intake of fluids, ability to void and to ambulate. This results in reduced intensity of postoperative care, decreased recovery time, and fewer side effects. Risks and complications of local or regional anesthesia include risk of allergy and systemic toxicity, severe hypotension secondary to vasodilatation, drug interactions, cardiac or respiratory depression or death. Systemic toxicity can occur if the needle tip accidentally enters a vein. Direct nerve injury, nerve damage from the needle tip, is also a potential complication.[33]

Although all types of anesthesia used in liposuction can be used at most locations performing liposuction, the use of local and regional anesthesia has allowed for a more rapid progression from the hospital setting, to doctors' offices and ambulatory surgical centers, reducing the cost of surgery. Resuscitative staff and equipment need to be in place should complications occur.

Intravenous (IV) sedation can be used in conjunction with local or regional anesthesia. Often administered by anesthesia personnel, the dose is low enough that a patient remains responsive and breathes without assistance. American Society of Plastic Surgery (ASPS) guidelines urge the use of anesthesia personnel whenever deep sedation is considered.[34]

General anesthesia may be used instead of local or regional anesthesia. Often, it is used for liposuction patients having a large volume of fat removed; having surgery on multiple sites, or for patients who do not want to be awake during the procedure.

Minor side effects from general anesthesia and surgery are common. They include: nausea, sore throat, headache, muscle aches or a "hang-over" feeling. These are most often not serious and resolve in hours or a few days after surgery. Risks and complications of general anesthesia include: airway trauma, bronchospasm, drug interactions, cardiac or respiratory depression, or death.

In a study of deaths in New York occurring after tumescent liposuction, Rao et. state that the most striking aspect of the deaths in their review is the incompleteness of explanation for the deaths of patients 1 and 2 (Appendix II).[8] They conclude that lidocaine toxicity was the probable cause of death. However, in a letter to the editor following publication of this study, Klein states that all five of the deceased patients received systemic anesthesia, which he defines as any form of general anesthesia that is likely to impair ventilation or protective airway reflexes.[35] He believes that systemic anesthesia, in the absence of any autopsy findings of lidocaine toxicity, was the most likely cause of death in the five patients.

Lidocaine Toxicity

There is disagreement over the maximum safe dose of lidocaine during tumescent liposuction. The fact that plasma lidocaine concentrations were not monitored in all but one of the reviewed studies may be considered a major design flaw. There appears to be some agreement that doses in excess of 35 mg/kg constitute a high dose. There is also agreement that a corresponding increase in the risk of lidocaine toxicity occurs with higher doses.

The Physicians' Desk Reference (PDR) states that the maximum safe dose for lidocaine hydrochloride with epinephrine should not exceed 7 mg/kg, with a maximum total dose not to exceed 500 mg, with the dosing recommendations being unchanged from the 1993 edition.[36] In response to this, Klein states that these dosing recommendations are valid when commercially available lidocaine with a strength of 1% or 2% is used, but that higher doses of diluted 0.05% or 0.1% strength can be used when infiltrated with epinephrine over a greater time period into the relatively avascular subcutaneous fatty tissue.[4] According to Klein, 35 mg/kg of lidocaine is considered by many to be a safe maximum dose, although he has used doses as high as 52 mg/kg without any apparent side effects. It should be noted that the recommendations in the PDR are based on dose-response studies of lidocaine serum concentrations. There are no comparable studies of 0.05 \ 0.1% lidocaine serum concentrations. Ostad et al. reported 55 mg/kg as a safe dose based on a subjective evaluation of 60 patients.[37] Two studies of lidocaine in tumescent liposuction revealed a nonlinear relationship between total lidocaine dose and peak plasma concentrations. The authors stated this may be attributable to the unequal volume of distribution of lidocaine in the subcutaneous tissue of each patient which resulted in potential absorption differences in each individual.[37,38]

A safety concern with this approach is the potential for plasma lidocaine concentrations to reach dangerous levels. Rubinstein outlines the progressively toxic effects of elevated blood lidocaine levels: at 3-6 \'b5g/mL, nystagmus, tongue/perioral numbness, and light headedness occur; at 5-9 \'b5g/mL, muscle twitching and tremors are seen; above 10 \'b5g/mL; cardiac depression and coma occur, followed by cardiovascular depression and cardiac arrest above 20 \'b5g/mL.[39]

Toxicity can develop even when plasma lidocaine levels are in the therapeutic range. Pitman describes the case of a patient who received 48.8 mg/kg.[40] The patient suffered a panic attack that began 8 hours after surgery and subsided spontaneously in 4 hours. The 12-hour plasma lidocaine level was 3.7 \'b5g/mL. Pitman believes that early central nervous system toxicity can occur in doses as low at 3 \'b5g/mL.

Pitman states that local anesthesia may be inadequate in cases where the lidocaine requirements are so high that they pose a risk of toxicity.[40] There are several situations where high doses of lidocaine, which Pitman defines as a dose exceeding 35 mg/kg, are needed to achieve complete local anesthesia: treatment of multiple areas, particularly in smaller patients, and work in areas of more richly innervated subdermal, and in areas where previous treatment and scarring limits diffusion. An alternative approach is to divide the operation in to two or more separate procedures.

As stated earlier, Rao et al. concluded that lidocaine toxicity was the probable cause of death of patients 1 and 2.[8] The authors emphasize the importance of the hepatic cytochrome P450 system, which is responsible for the enzymatic metabolism of lidocaine and most other drugs. The liver enzyme that metabolizes lidocaine, 3A4, can become saturated when absorption exceeds elimination. This can cause plasma lidocaine levels to increase rapidly. Other drugs that are metabolized by or inhibit P450 3A4 compete with lidocaine, thereby altering its metabolism. Midazolam competes with lidocaine for enzymatic metabolism. Midazolam's sedative effects may mask the symptoms of lidocaine toxicity until the onset of cardiovascular collapse.

There are several variables that determine the systemic absorption of lidocaine, and can influence plasma levels. These include the concentration of the drug, the degree of vasculature of the site of infiltration, the concomitant use of vasoconstrictive drugs, and the rate of infiltration. Infiltration of lidocaine with epinephrine delays absorption and plasma levels rise slowly, peaking as late as 10-14 hours after infiltration.[4] For outpatients, plasma levels may not peak until the patient is at home. Rapid infusion of lidocaine requires greater sedation to relieve the discomfort, thereby masking subjective signs of toxicity.[38] Physicians removing large volumes of aspirate (>5L) can push the lidocaine dosing envelope upward, even beyond 50 mg/kg.[41] Toxicity may also occur when additional lidocaine is administered for concurrent cosmetic surgeries.[42]

A review of several malpractice cases involving liposuction found suggested possible errors in the solution preparation.[43] Adding either the incorrect amount or concentration of lidocaine can result in accidental overdose. Using a standardized guideline for preparing the solution, preparation by a pharmacist, and review by two people could help prevent serious errors.

Fluid Balance

Controversy exits as to the IV fluid requirements in tumescent liposuction. Fluid balance problems, which can lead to hypervolemia and pulmonary edema, are potential complications with subcutaneous infusion of high volumes of tumescent solution. Volumes can potentially reach 7:1 (infiltrate to aspirate). Additionally, fluids may be administered intravenously which also adds to the volume load. While it seems that most of the solution will be aspirated out, up to 70% of excess fluid (including lidocaine if used), is left behind to be absorbed by the body.[9,44] Since there are no clear-cut guidelines for fluid administration in liposuction, a sound clinical understanding of fluid replacement and drug interactions as well as diligent patient monitoring by the operating physician and the anesthesia care team are crucial for the patient's safety.[9]

Trott et al. found that blood loss is roughly 1% in tumescent liposuction, and should not require fluid replacement.[9] The authors found a small percentage (14%) of patients experienced hypotension, and it is unknown if the cause was related to volume depletion, surgical manipulation (i.e. obstruction of venous return), or anesthesia (i.e. general, regional, and/or local).

Gilliland and Coates in a case study of pulmonary edema, suggested limiting intravenous replacement, monitoring urine output in large volume cases, and assuring anesthesia care staff are knowledgeable in using tumescent solution for local anesthesia to avoid this

complication.[45]

Proper patient selection and communication between the procedural physician and the anesthesia staff regarding fluid replacement are keys to maintaining volume status and patient safety.[9,46] The total volume of fluid (intravenous and tumescent solution) administered to the patient should be reviewed and compared to the total volume that came out of the patient (urine output, aspirate, fluid loss from incisions as well as blood loss for concomitant surgical procedures).[46]

Use of anesthesia personnel is recommended whenever deep sedation, large doses of lidocaine or both are considered.[44]The authors state that the role of lidocaine toxicity is underestimated, and potentially preventable events such as fluid imbalance and pulmonary edema demand improved monitoring, resuscitative and recuperative facilities in physician offices.

Physician Qualifications
Any medical doctor is permitted by virtue of their medical license to perform liposuction, including osteopathic doctors and dentists. In an increasingly commercialized marketplace, physicians and even non-physicians claim board certification and specialization in their advertising. Board certification refers to accreditation by one of the Accreditation Council for Graduate Medical Education (ACGME) recognized medical specialties (e.g. American Board of Plastic Surgery, American Board of Dermatology). Unfortunately, it is used, at times, synonymously with certification from ACGME accredited organizations where certification requirements may be as little as watching a training video or taking a weekend course. Formal training and experience are needed to perform tumescent liposuction.[22]

The documentary, "Cosmetic Surgery Gone Wrong," revealed the results of poorly done surgeries.[27] One patient developed gangrene after liposuction to the legs. The physician used a picklefork-shaped cannula causing damage to blood vessels and nerves. Amputation was averted but the resulting fibrous scarring caused difficulties with ambulation. A physician described increases in corrective surgeries in her practice. She also stated that in some weekend certification courses, physicians practice on a tomato - which is much different than working on real patients.

Venue
The majority of liposuctions are performed in hospitals, outpatient surgical centers and physician offices. When liposuction is performed outside the hospital setting, personnel and equipment should be on hand to manage emergencies. The facility should have an established policy and procedure concerning unanticipated patient transfer to an acute care hospital.

An analysis was conducted of statistics gained from the Physician Insurers Association of America (PIAA) Data Sharing Project database, a trade association of professional liability companies that insure about 60 percent of America's private physicians.[47] It found that 85% of plastic surgeons are indemnified against lipoplasty claims as compared to 2% of dermatologists whose coverage may also have restrictions on volume aspirated, body areas accessible and administration of sedation for lipoplasty. Since a greater percentage of plastic surgeons are indemnified compared to dermatologists, it is not unexpected that their specialty would bear a higher number of claims.

In a census survey of aesthetic plastic surgeons, it was reported that 77 percent of deaths occurred in physician offices and outpatient surgical centers, with 17 percent occurring in hospitals.[5]

Complications

Side effects from liposuction include injury to local tissues, leading to bruising, swelling and blood loss.

Complications reported in the reviewed literature include the following: palpable/visible irregularities, seroma, scar hyperpigmentation, skin necrosis, perforation of the abdomen or viscera, blood transfusion, moderate and severe aesthesia and adynamia, serious abdominal fluid accumulation, distal necrosis of the flap, ventricular fibrillation, pulmonary edema, pulmonary or fat emboli, lidocaine toxicity, fluid imbalance, congestive heart failure, seizures and death. Other possibilities are allergic reaction, lasting sensory changes, bleeding, blood clots in legs or lungs, pain, infection, and damage to axillary plexus or deeper structures.

Rao et al. stated venous stasis and thrombogenesis could potentially occur following extensive tumescent liposuction of the lower abdomen and extremities, and immobilization.[8] This procedure can cause impedance of venous flow and the release of tissue factors.

Negative outcomes from liposuction can result in physical disfigurement and disability as well as psychological scars. Patients have described feelings of anger, depression, and guilt over not accepting their pre-surgery bodies, or have been made to feel the bad result was their fault, rather than that of the procedure. Negative physical outcomes may lead to additional surgery.

There have been no studies done on the long-term effects of liposuction. It is believed that there are a fixed number of fat cells in the adult body. Liposuction reduces the number of fat cells in the area treated. Tightness created by the healing process may prevent fat from returning, but whatever fat cells remain, as well as those in untreated areas, can still expand with weight gain. Liposuction is not an alternative to diet and exercise.

Issues of Controversy

Physician qualifications
Although liposuction is practiced by several specialties, it is estimated that plastic surgeons and dermatologists perform the majority, approximately 450,000, liposuctions annually. As stated earlier, any medical doctor, osteopathic doctor or dentist can practice liposuction; there are no federal or state laws governing the specialty education a practitioner must attain to perform liposuction.

Sedation and tumescent solution formulation
Physicians use a variety of sedation methods and formulations for tumescent solution in liposuction. The preference of most dermatologists is to perform the procedure without intravenous sedation or intravenous fluid replacement while plastic surgeons often employ sedation and/or general or regional anesthesia. The volume of fluids and sedation infiltrated and/or administered intravenously, drug interactions, and concentration of epinephrine and/or lidocaine in the tumescent solution can lead to adverse events when improperly monitored.

In a letter to the editor following publication of Rao's NY study, Klein states that all five of the deceased patients received systemic anesthesia, which he believes in the absence of any autopsy findings of lidocaine toxicity, was the most likely cause of death in the five patients.[35] Klein believes that drugs that cause respiratory depression pose one of the greatest risks of anesthesia (patients are ventilated during anesthesia).

The American Society of Anesthesiologists state that anesthesia has been shown to be extraordinarily safe and that the currently accepted anesthesia related mortality rate is approximately 1:250,000 anesthetics.[48] The Institute of Medicine report 'To Err is Human' highlights the dramatic improvement in patient safety from advances in anesthesiology over the last 25 years.[49]

Venue
Hospital and surgical center procedures are governed by rules dealing with staffing, equipment, reporting and emergency procedures. Doctors performing the same operations in their offices are not accountable to such rules. They are not required to meet the same competency tests as

they would if they performed surgery in hospitals and surgical centers (e.g. residency, board certification, case numbers). Hospital-based surgery tends to be more intensive, extensive and prolonged than office based surgery by virtue of its acute care setting. Unsatisfactory cosmetic outcomes are expected to be more prevalent than in simpler, briefer office procedures. Serious complications, on the other hand, are less frequent as operators must pass peer review to have operating privileges. Moreover, trained staff and resuscitative equipment are at hand.[47]

Regulation vs. Voluntary Reporting
While hospitals and outpatient surgical centers are regulated; office-based surgery in the majority of states are not. Since liposuction is an elective and pay-out-of-pocket procedure, data is not collected as to how many liposuction procedures are performed, the complexity of procedures or resultant complications. Given the fatality rate and complications (including permanent scarring), the lack of easily accessible data, and the movement of surgical procedures away from the hospital and surgical centers into doctor's offices, it is apparent that regulations to protect patient safety have not kept pace. The publicity generated by reports of deaths in the popular press has prompted national and state medical societies to publish guidelines of care for liposuction in an effort to ward off national or state regulation.

Cost

Review of the available information indicates a wide range of fees for liposuction, from $2,000 to $10,000 depending upon the size of area(s) treated. Facility fees are not included in these estimates.

Conclusions

Liposuction is generally safe, provided patients are carefully selected, the facility is properly equipped and the physician has accredited training with special training and experience in liposuction.

Sound clinical judgment based on a clear understanding of the physiologic events surrounding subcutaneous infusion of fluids and anesthetics is crucial for patient safety.

Local, regional, and general anesthesia and combinations thereof are acceptable methods of sedation for liposuction.

Controversy exists over the role of lidocaine in the tumescent solution and its potential for toxicity. Liposuction can be safely performed in hospitals, surgical centers and physician offices depending upon the number of surgical incisions and volume removed.

The liposuction-related death rate is estimated to be 8.4 in 100,000, higher than the incidence rate of other elective procedures (1 in 100,000). Because mandatory reporting of liposuction-related complications or deaths does not exist, the actual incidence of these events is unknown.

Deaths and disfigurement due to the cosmetic surgical procedure of liposuction should be a matter for serious public concern.

Recommendations

Patients should carefully choose the physician and facility where liposuction is to be performed. They should inquire as to qualifications and experience of the entire surgical team, including the anesthesia staff. They should assure that the facility has adequate technology to care for them during the procedure and, in the event of a complication, to revive them.

Patients should determine what contingency plan the facility has in the event of an emergency. It should include a fully supplied crash cart, staff trained in resuscitation, and a provision for patient transfer to provide acute care.

Reassessment of drug absorption and interactions, fluid management, prothrombogenic factors and liposuction volume should be encouraged.

Outcomes data should be gathered by the Department of Health that includes mandatory reporting of 30-day major morbidity (e.g. myocardial infarction, migration of venous thrombi and pulmonary emboli) and mortality.

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Appendix I:

Search Strategy: Evidence for this report was obtained from a search in the MEDLINE, PreMEDLINE, Current Contents, and EMBASE databases spanning 1985 to March 2002. Search terms included lidocaine, lidocaine toxicity, tumescent liposuction, ultrasound-assisted, and tumescent. Studies were evaluated if they utilized a control group or if they included a sample size greater than 40.

Appendix II - Background Data on Four Patients Who Died After Tumescent Liposuction*

Key:IV, intravenous; PO, oral; SC, subcutaneous infusion; Asp, aspirate; epi, epinephrine; CA, cardiac arrest; pt(s), patient(s)

\plain\f4 \fs18\b Pt #	Ht (m)	Wt (kg)	Anesthetic Adjunct	IV	Lidocaine Dose (mg/kg)	epi (mg)	Duration of Procedure (hours)	Time to CA (hours)	Lidocaine Concentration
1	1.7	100	Midazolam (5 mg IV), Meperidine (100 mg IV), propofol (20 mg IV), isoflurane, nitrous oxide	3	\tab 10	2	2.5*	2.5	Blood 5.2 mg/L, Brain 4.7 mg/kg, liver: 5.2 mg/kg, peritoneal fluid 17 mg/kg
2	1.57	84	Midazolam (5 mg IV), fentanyl 150 µg IV) methohexital (40 mg IV), droperidol (125 mg IV)	1.7	14.3	1.2	2.3*	2.3	Blood: 2 mg/L
3	1.68	\tab 95.5	Morphine (18 mg IV), diphen-hydramine (25 mg IV), oxycodone (2 tablets PO)	7.3	31.4	3	4.5	>48	NA
4	1.83	1.83	Meperidine, zolpidem, promethazine	NA	40	NA	7	25	Blood 2.9 mg/L, brain 4.9 mg/kg, liver 14.8 mg/kg, gastric

								contents 2.7 mg/kg

* Data provided by Rao et al.[8]

Appendix III. Liposuction Complications and Fatalities:\plain\f4\fs18 \plain\f4\fs18\b Case and Newsarticle Reports

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	Authors	Patient	Type of Liposuction	Complications	Outcome
Gilliland M, Coates N (1997)[45] Tumescent Liposuction Complicated by Pulmonary Edema	55 yr old 175 lb, 6ft 1in male. Had 3 previous liposuction procedures.	Tumescent w/ gen anesthesia, operation 2.5 hours.	O2 saturation dropped 20 min postoperatively. Pulmonary medicine consult; pt transferred to ICU, chest x-rayed, EKG done, furosemide given.	Chest xray next day clear. Pt released.	
Talmor et al (1997)[51] Intestinal Perforation After Suction Lipoplasty	50 yr old female	Tumescent Liposuction and face-lift	Nausea, vomiting, inability to tolerate oral intake, diffuse abdominal pain 24 hrs postop. Admitted on Day 3 with fever chill, no bowel movement since surgery.	6 enterotomies of small bowel requiring removal of 30 cm. Difficult recovery period. Discharged Day 25	
Buescher, TM (2000)[52] Paraspinous Muscle Hemorrhage as a Potential Source of Liposuction Mortality	mid 40s female	Liposuction with full abdominoplasty\tab	Pt reported persistent bleeding from cannula incisions in recovery. Went into shock after discharge. Paraspinous muscle hemorrhage required sutures.	Pt recovered after ICU stay for airway swelling and blood transfusions	
Barillo DJ et al (1998)[53] Fatal and	48 yr old female	Liposuction by family practitioner on 3 sites, outpatient.	Fever, chills, dyspnea, nausea, vomiting, foul-smelling drainage on day 2. Admitted to ER on day 7. Treated for	Death due top adult respiratory distress syndrome and organ failure.	

near-fatal complications of Lipo	31 yr old female	Tumescent w/ general anesthesia at 3 sites	necrotizing fasciitis over 9% of body area. Fever, wound-related pain on day 4. Treated for necrotizing fasciitis.	Lengthy recovery after grafts on 22% of body surface area.
Gibbons MD et al (1998)[54] Necrotizing fasciitis after tumescent liposuction	31 yr old female cigarette smoker, otherwise healthy	Tumescent lipo, multiple sites\tab	Presented to ER with weakness, fever and red painful nodule on left flank. Pus drained from all port sites. Treated for necrotizing fasciitis.	Recovery after radical debridement and skin grafting\tab
HetimannC et al (2000)[55] Rapidly fatal necrotizing fasciitis after aesthetic liposuction	28 yr old female	Fever, chills, nausea, vomiting, diarrhea on day 2. Treated begun for necrotizing fasciitis. Septic shock on day 3.	Death due to multi-organ failure on day 6.	
Umeda et al (2000)[56]BR> Toxic Shock Syndrome after Suction Lipectomy	27 yr old female	Liposuction at 3 sites, outpatient\tab	Wound pain on day 1. Diagnosed with toxic shock syndrome and necrotizing fasciitis.	Difficult recovery included skin grafts and psychiatric care to help pt adapt.
Klein JA, Kassarjdian N (1997)[57] 39 yr old female	Tumescent liposuction 2 surgeries 1 mo apart. 3 sites suctioned at surgery.	Lidocaine toxicity symptoms after surgery. Suspected drug interaction with oral medication (sertraline).	Admitted to hospital for observation overnight. Released next day.	
Men's Health (Apr 1999)[58] "Lipo Sucks, Then You Die"	51 yr old male 50 yr old male	11 hour multiple site surgery including liposuction, outpatient Liposuction of 10 lbs.	Med examiner report stated pt was found hooked to empty O2 tank, had excessive amt of respiratory depressants in system. Fat embolism	Death Death
Florida Sun-Sentinel April 4, 2001[59] "Naples		Liposuction on	News article did	

Woman Dies Day After Liposuction, Laser Surgery"	57 yr old female	stomach & hips, laser facial surgery using gen anesthesia	not state complications	Death day after surgery
People Oct 30, 2000[60] "Dying to Be Thin" pp 108-118.	47 yr old female 33 yr old female	Liposuction at multiple sites and face/brow lift. Outpatient using gen anesthesia Hi vol liposuction on 6 sites; outpatient	Fluid overload, blood loss Dizziness, shortness of breath, cardiac arrest.	Death due to cardiac arrest. Death due to brain swelling and lack of O2.

Appendix IV: Florida Administrative Code

Florida Administrative Code
Chapter 64 - Department of Health
Rule 64B8-9.009

64B8-9.009 Standard of Care for Office Surgery.

NOTHING IN THIS RULE RELIEVES THE SURGEON OF THE RESPONSIBILITY FOR MAKING THE MEDICAL DETERMINATION THAT THE OFFICE IS AN APPROPRIATE FORUM FOR THE PARTICULAR PROCEDURE(S) TO BE PERFORMED ON THE PARTICULAR PATIENT.
(1) Definitions.
(a) Surgery. For the purpose of this rule, surgery is defined as any manual or operative procedure, including the use of lasers, performed upon the body of a living human being for the purposes of preserving health, diagnosing or curing disease, repairing injury, correcting deformity or defects, prolonging life, relieving suffering or any elective procedure for aesthetic, reconstructive or cosmetic purposes, to include, but not be limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or organ, including a closed as well as an open reduction of a fracture; extraction of tissue including premature extraction of the products of conception from the uterus; insertion of natural or artificial implants; or an endoscopic procedure with use of local or general anesthetic.
(b) Surgeon. For the purpose of this rule, surgeon is defined as a licensed physician performing any procedure included within the definition of surgery.
(c) Equipment. For the purpose of this rule, implicit within the use of the term of equipment is the requirement that the specific item named must meet current performance standards.
(d) Office surgery. For the purpose of this rule office surgery is defined as surgery which is performed outside a hospital, an ambulatory surgical center, abortion clinic, or other medical facility licensed by the Department of Health, the Agency for Health Care Administration, or a successor agency. Office surgical procedures shall not be of a type that generally result in blood loss of more than ten percent of estimated blood volume in a patient with a normal hemoglobin; require major or prolonged intracranial, intrathoracic, abdominal, or major joint replacement procedures, except for laparoscopic procedures; directly involve major blood vessels; or are generally emergent or life threatening in nature.

(2) General Requirements for Office Surgery.
(a) The surgeon must examine the patient immediately before the surgery to evaluate the risk of anesthesia and of the surgical procedure to be performed. The surgeon must maintain complete records of each surgical procedure, as set forth in Rule 64B8-9.003, F.A.C., including anesthesia records, when applicable and the records shall contain written informed consent from the patient reflecting the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists, i.e.,

anesthesiologist, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C.
(b) The requirement set forth in paragraph (2)(a) above for written informed consent is not necessary for minor Level I procedures limited to the skin and mucosa.
(c) The surgeon must maintain a log of all Level II and Level III surgical procedures performed, which must include a confidential patient identifier, the type of procedure, the type of anesthesia used, the duration of the procedure, the type of post-operative care, and any adverse incidents, as identified in Section 458.351, F.S. The log and all surgical records shall be provided to investigators of the Department of Health upon request.
(d) In any liposuction procedure, the surgeon is responsible for determining the appropriate amount of supernatant fat to be removed from a particular patient. A maximum of 4000 cc supernatant fat may be removed by liposuction in the office setting. A maximum of 50 mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting - 292
(e) Liposuction may be performed in combination with another separate surgical procedure during a single Level II or Level III operation, only in the following circumstances:

1. When combined with abdominoplasty, liposuction may not exceed 1000 cc of supernatant fat.
2. When liposuction is associated and directly related to another procedure, the liposuction may not exceed 1000 cc of supernatant fat.
3. Major liposuction in excess of 1000 cc supernatant fat may not be performed in a remote location from any other procedure.

(f) For elective cosmetic and plastic surgery procedures performed in a physician's office, the maximum planned duration of all surgical procedures combined must not exceed 8 hours. Except for elective cosmetic and plastic surgery, the surgeon shall not keep patients past midnight in a physician's office. For elective cosmetic and plastic surgical procedures, the patient must be discharged within 24 hours of presenting to the office for surgery; an overnight stay is permitted in the office provided the total time the patient is at the office does not exceed 23 hours and 59 minutes including the surgery time. An overnight stay in a physician's office for elective cosmetic and plastic surgery shall be strictly limited to the physician's office. If the patient has not recovered sufficiently to be safely discharged within the timeframes set forth, the patient must be transferred to a hospital for continued post-operative care.
(g) The Board of Medicine adopts the "Standards of the American Society of Anesthesiologists for Basic Anesthetic Monitoring," approved by House Delegates on October 21, 1986, and last amended on October 21, 1998, as the standards for anesthetic monitoring by any qualified anesthesia provider.

1. These standards apply to general anesthetics, regional anesthetics, and monitored anesthesia care (Level II and III as defined by this rule) although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible supervising physician or anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. This set of standards address only the issue of basic anesthesia monitoring, which is one component of anesthesia care.
2. In certain rare or unusual circumstances some of these methods of monitoring may be clinically impractical, and appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. For purpose of this rule, "continual" is defined as "repeated regularly and frequently in steady rapid succession" whereas "continuous" means "prolonged without any interruption at any time."
3. Under extenuating circumstances, the responsible supervising physician or anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a

note in the patient's medical record. These standards are not intended for the application to the care of the obstetrical patient in labor or in the conduct of pain management.

a. Standard I.
I. Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics, and monitored anesthesia care.
II. OBJECTIVE. Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel, which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the supervising physician or anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

b. Standard II.
I. During all anesthetics, the patient's oxygenation, ventilation, circulation, and temperature shall be continually evaluated.
II. OXYGENATION.
(A) OBJECTIVE. To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.
(B) METHODS.
(I) Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*
(II) Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as a pulse oximetry shall be employed.* Adequate illumination and exposure of the patient are necessary to assess color.*
III. VENTILATION.
(A) OBJECTIVE. To ensure adequate ventilation of the patient during all anesthetics.
(B) METHODS.
(I) Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure, or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*.- 293
(II) When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a postoperative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.*
(III) When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.
(IV) During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs.
IV. CIRCULATION.
(A) OBJECTIVE. To ensure the adequacy of the patient's circulatory function during all anesthetics.
(B) METHODS.
(I) Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*
(II) Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*
(III) Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse,

auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.
V. BODY TEMPERATURE.
(A) OBJECTIVE. To aid in the maintenance of appropriate body temperature during all anesthetics.
(B) METHODS. Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated, or suspected.
(h) The surgeon must assure that the post-operative care arrangements made for the patient are adequate to the procedure being performed as set forth in Rule 64B8-9.007, F.A.C. Management of post surgical care is the responsibility of the operating surgeon and may be delegated only as set forth in subsection 64B8-9.007(3), F.A.C. If there is an overnight stay at the office in relation to any surgical procedure:

1. The office must provide at least two (2) monitors, one of these monitors must be certified in Advanced Cardiac Life Support (ACLS), and maintain a monitor to patient ratio of at least 1 monitor to 2 patients. Once the surgeon has signed a timed and dated discharge order, the office may provide only one monitor to monitor the patient. The monitor must be certified in Advanced Cardiac Life Support. The full and current crash cart required below must be present in the office and immediately accessible for the monitors.
2. The surgeon must be reachable by telephone and readily available to return to the office if needed. For purposes of this subsection, "readily available" means capable of returning to the office within 15 minutes of receiving a call.

(i) A policy and procedure manual must be maintained in the office, updated annually, and implemented. The policy and procedure manual must contain the following: duties and responsibilities of all personnel, quality assessment and improvement systems comparable to those required by Rule 59A-5.019, F.A.C.; cleaning, sterilization and infection control, and emergency procedures. This applies only to physician offices at which Level II and Level III procedures are performed.
(j) The surgeon shall establish a risk management program that includes the following components:

The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,

1. The identification of trends or patterns of incidents,
2. The development of appropriate measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients, and
3. The documentation of these functions and periodic review no less than quarterly of such information by the surgeon.

(k) The surgeon shall report to the Department of Health any adverse incidents that occur within the office surgical setting.
This report shall be made within 15 days after the occurrence of an incident as required by Section 197, Chapter 99-397, Laws of Florida.
(l) A sign must be prominently posted in the office which states that the office is a doctor's office regulated pursuant to the rules of the Board of Medicine as set forth in Rule Chapter 64B8, F.A.C. This notice must also appear prominently within the required patient informed consent.
(3) Level I Office Surgery.
(a) Scope. Level I office surgery includes the following:

Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient.

1. Liposuction involving the removal of less than 4000 cc supernatant fat is permitted.

2. Incision and drainage of superficial abscesses, limited endoscopies such as proctoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple fractures or small joint dislocations (i.e., finger and toe joints).- 294
3. Pre-operative medications not required or used other than minimal pre-operative tranquilization of the patient; anesthesia is local, topical, or none. No drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient is permitted in level I Office Surgery.
4. Chances of complication requiring hospitalization are remote.

(b) Standards for Level I Office Surgery.
1. Training Required. Surgeon's continuing medical education should include: proper dosages; management of toxicity or hypersensitivity to regional anesthetic drugs. Basic Life Support Certification is recommended but not required.
2. Equipment and Supplies Required. Oxygen, positive pressure ventilation device, Epinephrine (or other vasopressor), Corticoids, Antihistamine and Atropine if any anesthesia is used.
3. Assistance of Other Personnel Required. No other assistance is required, unless the specific surgical procedure being performed requires an assistant.

(4) Level II Office Surgery.
(a) Scope.
1. Level II Office Surgery is that in which peri-operative medication and sedation is used intravenously, intramuscularly, or rectally, thus making intra and post-operative monitoring necessary. Such procedures shall include, but not be limited to: hemorrhoidectomy, hernia repair, reduction of simple fractures, large joint dislocations, breast biopsies, colonoscopy, and liposuction involving the removal of up to 4000 cc supernatant fat.
2. Level II Office surgery includes any surgery in which the patient is placed in a state which allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal command and/or tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by this definition.

(b) Standards for Level II Office Surgery.
1. Transfer Agreement Required. The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician does not have staff privileges to perform the same procedure as that being performed in the outpatient setting at a licensed hospital within reasonable proximity. "Reasonable proximity" is defined as not to exceed thirty (30) minutes transport time to the hospital.
2. Training Required. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board eligibility by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to establish comparable background, training, and experience. The surgeon and one assistant must be currently certified in Basic Life Support and the surgeon or at least one assistant must be currently certified in Advanced Cardiac Life Support or have a qualified anesthesia provider practicing within the scope of the provider's license manage the anesthesia.
3. Equipment and Supplies Required.
a. Full and current crash cart at the location the anesthetizing is being carried out. The crash cart must include, at a minimum, the following resuscitative medications:

I. Adrenalin (epinephrine) 1:10,000 dilution; 10ml
II. Adrenalin (epinephrine) 1:1000 dilution; 1ml
III. Atropine 0.1mg/ml; 5ml
IV. Benadryl (diphenhydramine)
V. Calcium chloride 10%; 10ml
VI. Dextrose 50%;
VII. Dilantin (phenytoin)
VIII. Dopamine
IX. Heparin
X. Inderal (propranolol)
XI. Isuprel
XII. Lanoxin (digoxin)
XIII. Lasix (furosemide)
XIV. Xylocaine (lidocaine)
XV. Magnesium sulfate 50%
XVI. Narcan (naloxone)
XVII. Pronestyl (procainamide)
XVIII. Sodium bicarbonate 50mEq/50ml
XIX. Solu-medrol (methylprednisolone)
XX. Verapamil hydrochloride
XXI. Romazicon

b. Suction devices, endotracheal tubes, laryngoscopes, etc.
c. Positive pressure ventilation device (e.g. Ambu) plus oxygen supply.- 295
d. Double tourniquet for the Bier block procedure.
e. Monitors for blood pressure/EKG/Oxygen saturation.
f. Emergency intubation equipment.
g. Adequate operating room lighting.
h. Emergency power source able to produce adequate power to run required equipment for a minimum of two (2) hours.
i. Appropriate sterilization equipment.
j. IV solution and IV equipment.

4. Assistance of Other Personnel Required. The surgeon must be assisted by a qualified anesthesia provider as follows: An Anesthesiologist, Certified Registered Nurse Anesthesist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C., or a registered nurse may be utilized to assist with the anesthesia, if the surgeon is ACLS certified. An assisting anesthesia provider cannot function in any other capacity during the procedure. If additional assistance is required by the specific procedure or patient circumstances, such assistance must be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, a licensed registered nurse with post-anesthesia care unit experience or the equivalent, credentialed in Advanced Cardiac Life Support or, in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia.

(5) Level IIA Office Surgery.
(a) Scope. Level IIA office surgeries are those Level II office surgeries with a maximum planned duration of 5 minutes or less and in which chances of complications requiring hospitalization are remote.
(b) Standards for Level IIA Office Surgery.

1. The standards set forth in subsection 64B8-9.009(4), F.A.C., must be met except for the requirements set forth in subparagraph 64B8-9.009(4)(b)4., F.A.C., regarding assistance of other personnel.
2. Assistance of Other Personnel Required. During the procedure, the surgeon must be assisted by a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or by a licensed registered nurse or a

licensed practical nurse. Additional assistance may be required by specific procedure or patient circumstances. Following the procedure, a physician or physician assistant who is licensed pursuant to Chapter 458 or 459, F.S., or a licensed registered nurse must be available to monitor the patient in the recovery room until the patient is recovered from anesthesia. The monitor must be certified in Advanced Cardiac Life Support, or, in the case of pediatric patients, Pediatric Advanced Life Support.

(6) Level III Office Surgery.

(a) Scope.

1. Level III Office Surgery is that surgery which involves, or reasonably should require, the use of a general anesthesia or major conduction anesthesia and pre-operative sedation. This includes the use of:
   a. Intravenous sedation beyond that defined for Level II office surgery;
   b. General Anesthesia: loss of consciousness and loss of vital reflexes with probable requirement of external support of pulmonary or cardiac functions; or
   c. Major conduction anesthesia.
2. Only patients classified under the American Society of Anesthesiologist's (ASA) risk classification criteria as Class I or II are appropriate candidates for Level III office surgery.
   a. All Level III surgeries on patients classified as ASA III and higher are to be performed only in a hospital or ambulatory surgery center.
   b. For all ASA II patients above the age of 40, the surgeon must obtain, at a minimum, an EKG and a complete workup performed prior to the performance of Level III surgery in a physician office setting. If the patient is deemed to be a complicated medical patient, the patient must be referred to an appropriate consultant for an independent medical clearance. This requirement may be waived after evaluation by the patient's anesthesiologist.

(b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:

1. Training Required.
   a. The surgeon must have staff privileges at a licensed hospital to perform the same procedure in that hospital as that being performed in the office setting or must be able to document satisfactory completion of training such as Board certification or Board qualification by a Board approved by the American Board of Medical Specialties or any other board approved by the Board of Medicine or must be able to demonstrate to the accrediting organization or to the Department comparable background, training and experience. In addition, the surgeon must have knowledge of the principles of general anesthesia. If the anesthesia provider is not an anesthesiologist, there must be a licensed M.D., or D.O., anesthesiologist, other than the surgeon, to provide direct supervision of the administration and maintenance of the anesthesia.
   b. The surgeon and one assistant must be currently certified in Basic Life Support and the surgeon or at least one assistant must be currently certified in Advanced Cardiac Life Support.
2. Emergency procedures related to serious anesthesia complications should be formulated, periodically reviewed, practiced, updated, and posted in a conspicuous location.
3. Equipment and Supplies Required.- 296
   a. Equipment, medication, including at least 36 ampules of dantrolene on site, and monitored post-anesthesia recovery must be available in the office.
   b. The office, in terms of general preparation, equipment, and supplies, must be comparable to a freestanding ambulatory surgical center, including, but not limited to, recovery capability, and must

have provisions for proper record keeping.
c. Blood pressure monitoring equipment; EKG; end tidal CO 2 monitor; pulse oximeter, precordial or esophageal stethoscope, emergency intubation equipment and a temperature monitoring device.
d. Table capable of trendelenburg and other positions necessary to facilitate the surgical procedure.
e. IV solutions and IV equipment.

4. Assistance of Other Personnel Required. An Anesthesiologist, Certified Registered Nurse Anesthetist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(c)6., F.A.C., must administer the general or regional anesthesia and an M.D., D.O., Registered Nurse, Licensed Practical Nurse, Physician Assistant, or Operating Room Technician must assist with the surgery. The anesthesia provider cannot function in any other capacity during the procedure. A physician licensed under Chapter 458 or 459, F.S., a licensed physician assistant, or a licensed registered nurse with post-anesthesia care unit experience or the equivalent, and credentialed in Advanced Cardiac Life Support, or in the case of pediatric patients, Pediatric Advanced Life Support, must be available to monitor the patient in the recovery room until the patient has recovered from anesthesia.

Specific Authority 458.309(1), 458.331(1)(v) FS. Law Implemented 458.331 (1)(g), (t), (v), (w), 458.351 FS. History\endash New 2-1-94, Amended 5-17-94, Formerly 61F6-27.009, Amended 9-8-94, 11-15-94, Formerly 59R-9.009, Amended 2-17-00, 12-7-00, 2-27-01, 8-1-01, 8-12-01, and 3-25-02.

Appendix V: Public Comment

The following was submitted to HTAC during the public comment period on this assessment. The workgroup and full Committee reviewed each statement and incorporated them into the report as the Committee deemed appropriate.

Minnesota Association of Nurse Anesthetists

Ms. Brenda Holden March 26, 2002
Executive Director
Health Technology Advisory Committee
Minnesota Department of Health
121 E. 7th Place
St. Paul, MN 55101

Comments on the Tumescent Liposuction Report

My name is Lisa Citak, CRNA, MS. As President of the Minnesota Association of Nurse Anesthetists I am commenting on behalf of all Minnesota CRNAs. In Minnesota, CRNAS administer anesthesia for all types of surgical procedures, using all anesthesia techniques and practice in every setting in which anesthesia is delivered, from free standing surgical facilities to university-based medical centers. In Minnesota, all 126 hospital facilities use CRNA services, and of these, 88 facilities use CRNAs exclusively for their anesthesia services.

We agree with the overall conclusions and recommendations of the March 12 HTAC Tumescent Liposuction report. Patients should carefully choose the physician and facility where liposuction is to be performed, inquiring as

to the qualifications and experience of the entire surgical team, including the anesthesia staff. This recommendation should apply to any surgical or medical procedure.

When discussing safety issues the report correctly identifies proper patient selection, a sound clinical understanding of fluid replacement and drug interactions as well as diligent patient monitoring and communication between the operating physician and the anesthesia staff as crucial for the patient's safety. In the discussion of anesthesia and safety issues surrounding tumescent liposuction, the report does not recommend one type of anesthesia provider over the other. However, the report includes in Appendix IV the State of Florida Board of Medicine regulations for office-based surgery that include an anesthesiologist supervision requirement for Level III office surgeries. Level III include surgery that "involves, or reasonably should require, the use of general anesthesia or major conduction anesthesia."

The anesthesia requirements within the Florida Board of Medicine regulation for office-based surgery have generated controversy and numerous legal challenges. As stated in the HTAC report, the regulations were a result of concern over a number of deaths following liposuction in Florida. In fact, physician anesthesiologists provided the anesthetic in a number of these cases. There were also instances of liposuction being performed by non-physicians.

Although we are not completely opposed to the idea of regulating office based surgery, we cannot support unreasonable requirements such as those in Florida that are not based on credible scientific evidence and serve only to restrict physicians from utilizing CRNAs services in offices. None of the three national organizations that accredit office surgical facilities requires nurse anesthetists to be supervised by an anesthesiologist. There are no other state or federal laws requiring supervision of nurse anesthetists by anesthesiologists in an office setting. Evidence presented to the Florida courts did not produce any Florida statistics demonstrating that anesthesiologist supervision improves anesthesia care outcomes.

CRNA practice in Minnesota is currently governed by the Board of Nursing with respect to the 1999 Minnesota Nurse Practice Act. This law defines registered nurse anesthetist practice to be " the provision of anesthesia care and related services within the context of collaborative management, including selecting, obtaining, and administering drugs and therapeutic devices to facilitate diagnostic, therapeutic and surgical procedures upon request, assignment or referral by a patient's physician, dentist or podiatrist." (Minnesota Statutes section 148.171, subd.21). Furthermore, on April 19, 2002, Governor Ventura elected to "opt out" of the federal requirement of physician supervision of nurse anesthetists, citing, "this is consistent with Minnesota state law and in the best interests of Minnesota citizens."

Our national organization, the American Association of Nurse Anesthetists (AANA) has developed the most extensive and thorough office-based anesthesia standards of any anesthesia provider to date. CRNAs were the very first to embark upon this topic as a major safety/risk management initiative. By reviewing these published standards of the AANA, it is clear that CRNAs hold the standard of care in an office to be the same as that of inpatient settings. We would be happy to share these standards and protocols, if requested.

Thank you for the opportunity to comment on the HTAC Tumescent

Liposuction report. If you have any questions, please don't hesitate to contact me. The Minnesota Association of Nurse Anesthetists looks forward to insuring safe, high quality patient care in the office-based practice.

Sincerely,

Lisa A. Citak, CRNA, MS
President,
Minnesota Association Nurse Anesthetists

MAYO

Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Clark C. Otley, M.D.
Dermatology
Dermatologic Surgery

April 12, 2002

Ms. Jackie Harte
Project Team Leader
Health Technology Advisory Committee
121 East 7th Place, Suite 400
P.O. Box 64975
St. Paul, MN 55164-0975

Dear Ms. Harte:

Thank you kindly for the opportunity to review the HTAC report on tumescent liposuction. Overall, I think the quality of the report was very good. I would like to make a couple public comments on the presentation.

1. It is important to highlight that there have been no reported deaths from tumescent liposuction utilizing tumescent anesthesia alone. Deaths have only occurred in liposuction cases performed with either general anesthesia or sedation, with some cases employing tumescent technique additionally but not alone. As noted in your report, commonly administered sedatives have pharmacologic interactions with hepatic metabolism and may be primarily responsible for adverse reactions noted in cases utilizing both sedatives and tumescent anesthesia. Because purely tumescent anesthesia is the most cost-effective method for anesthesia for liposuction, it is important to be clear that the safety record with pure tumescent anesthesia is unparalleled so as to clarify that this is a well-documented safety method for liposuction anesthesia. Rather than highlighting the controversy surrounding lidocaine in tumescent anesthesia, based on the above-mentioned point, I think highlighting the controversy over the role of sedation in combination with lidocaine and tumescent anesthesia is the most important issue surrounding the safety administration of anesthesia in liposuction.

2. On page 9, sentence 13, I would disagree with your statement that an advantage of general anesthesia is minimal blood loss and a low complication rate. Prior to the introduction of tumescent anesthesia it was routine for patients to receive blood transfusions due to the extensive blood loss associated with liposuction performed under general anesthesia. Also, as noted previously, the mortality associated with liposuction is noted in cases performed with sedatives and general anesthetics rather than with tumescent liposuction. Also, it is clear that patients receiving multiple procedures at the time of liposuction, which are generally performed under general anesthetic, have significantly higher risks of complications including death.

Thank you for the opportunity to comment publicly on the HTAC tumescent liposuction report. If you have any questions regarding my comments, please feel free to contact me.

Sincerely,

Clark C. Otley, M.D.
CCO/amc

cc: Stephen Mandy, M.D.,
President of the American Society for Dermatologic Surgery

cc: William Coleman, M.D.,
Editor in Chief of Dermatology Surgery

American Academy of Dermatology Association Raymond L. Cornelison, M.D.
1350 1 St NW Ste 880 President-Elect Washington DC 20005-3319
Phone 202/842-3555 Clay J. Cockerell, M.D. Fax 202/842-4355 Secretary-Treasurer Web Site www.aadassociation.org Neil A. Swanson, M.D. Vice President David M. Pariser, M.D. Assistant Secretary-Treasurer

April 16, 2002
Joseph L. Jorizzo, M.D.
Vice President-Elect
Thomas P. Conway
Executive Director
Ms. Nancy Cusick
Minnesota Health Technology Advisory Committee
121 East 7th Place, Suite 400
St Paul, MN 55101

Dear Ms. Cusick:

We are in receipt of the conclusions reached by the Minnesota Health Technology Advisory Committee in regard to tumescent liposuction. On behalf of over 10,000 dermatologists nationwide, I would like to provide you with appropriate comments based on our review.

The report referenced a survey of plastic surgeons performing liposuction, although there are other cosmetic surgeons, including dermatologic surgeons, who perform tumescent liposuction for their patients on a regular

basis.

You reference the need for "accredited training" in your conclusions. What is your definition of accredited training? Medical residency training? Specialty course training? This is an important concept.

Data pertaining to adverse patient incidents, gathered from every state where this information is available, shows that dermatologists have an outstanding safety record. The data further shows that adverse incidents in medical offices where liposuction is performed have much higher liklihood of experiencing adverse patient incidents when:

- Higher levels of anesthesia are utilized (including general anesthesia)
- Multiple forms of anesthesia are utilized together (such as general anesthesia with turnescent anesthesia)
- Multiple procedures are performed in conjunction with liposuction, particularly when those procedures are invasive and aggressive

Lidocaine toxicity has not been a problem in turnescent anesthesia nor is it likely to become one when appropriate levels are utilized (up to 55 mg/kg of body weight). This idea is largely the result of a study that was published in the Journal of the American Medical Association (JAMA) several years ago. The study was seriously flawed however and we would be happy to address that issue more directly as necessary. Tumescent anesthesia has many new applications for medical (not only cosmetic) procedures.

The most aggressive form of anesthesia that the AADA currently recommends for use in conjunction with procedures such as liposuction in medical offices is "pure tumescent anesthesia". This involves no additional forms of anesthesia utilized in conjunction to the turnescent (lidocaine/epinephrine) formula, with the exception of minimal pre-operative sedation. As your report concludes that a number of different forms of anesthesia are acceptable for use with liposuction ("local, regional and general"), we would point out to you that existing adverse incident data clearly indicates a danger associated with higher levels of anesthesia and multiple forms of anesthesia (as previously referenced).

We appreciate the opportunity to provide comments pertaining to the report and will be more than happy to work with you as needed and to provide you with any information that we have available in regard to this important issue. Our clinical guidelines, as well as several articles pertaining to the safety of turnescent anesthesia and adverse patient incidents are attached.

Sincerely,

Margaret E. Parsons, MD, Chair
AADA Government Affairs Committee

The following attachments were included and have been omitted in the interest of saving space. They can be obtained by writing:
American Academy of Dermatology Association
1350 1 St NW, Ste 880
Washington DC 20005-3319
Phone 202-842-3555
Website http://www.aadassociation.org\plain\f5\fs18

1. Guidelines of Care for Liposuction, dated December 10, 2000.
2. AADA Issue Brief, Office-Based Medicine.
3. ADA Issue Brief, Office-Based Medicine-Liposuction.
4. Article by Ostad A, Kageyama N, May RL. Tumescent Anesthesia with a Lidocaine Dose of 55mg/kg is Safe for Liposuction. Dermatol Surg 1996;22:921-927.
5. Article by Hanke CW, Bernstein G, Bullock S. Safety of tumescent liposuction in 15,336 patients. Dermatol Surg. 1995;21:459-462.\plain\f4\fs18\b

Minnesota Dermatological Society

April 16, 2002

Ms. Nancy Cusick
Minnesota Health Technology Advisory Committee
121 East 7th Place, Suite 400
St. Paul, MN 55101

Dear Ms. Cusick:

In response to the recently released report pertaining to Tumescent Liposuction produced by the Minnesota Health Technology Advisory Committee, and on behalf of the Minnesota Dermatological Society, representing 125 dermatologists in Minnesota, I would like to provide the following comments.

In regard to the safety of tumescent liposuction, the available data shows that dermatologists throughout the nation utilizing turnescent anesthesia have an excellent safety record. To date, there have been no adverse patient incidents to our knowledge where pure tumescent anesthesia was properly administered and very few adverse patient incidents (and those incidents were minimal) where tumescent anesthesia was improperly administered. Your conclusions mention a concern about the potential toxicity of lidocaine, and while any anesthetic at improper doses can be toxic, the available scientific data pertaining to the appropriate use of lidocaine in tumescent anesthesia (documents attached) strongly indicates that properly utilized, lidocaine is safe and effective.

Tumescent anesthesia is one of the forms of anesthesia that is currently utilized in the performance of liposuction, although the potential applications for the use of tumescent anesthesia go far beyond liposuction and cosmetic procedures. Tumescent anesthesia in fact, was invented and developed by Jeffrey A. Klein, MD, a dermatologist in California. The appropriate use of the technique however, specifically excludes the use of additional anesthesia medications at dosages that have a significant risk for impairing the protective airway passages or for suppressing the respiratory drive. Tumescent liposuction is a method for performing liposuction surgery under local anesthesia. We would therefore take issue with your assertion that "local, regional and general anesthesia and combinations thereof are acceptable methods of sedation for liposuction." In fact, the only safe, proven method for office-based anesthesia in the office setting in regard to liposuction is in conjunction with pure, tumescent anesthesia (no additional anesthesia except minimal pre-operative sedation). In some cases however, physicians utilize "conscious sedation", where a patient is conscious

although slightly more sedated and there have been very few adverse patient incidents in conjunction with conscious sedation in medical offices. A review of the current available data pertaining to adverse patient incidents and liposuction, nationwide, strongly suggests that problems in medical offices are usually much more likely when the following are utilized:

1. Higher levels of anesthesia, including major conduction (general) anesthesia.
2. Multiple forms of anesthesia utilized concurrently.
3. Multiple and particularly invasive and aggressive procedures performed in conjunction with liposuction (such as abdominoplasty in conjunction with Iiposuction).

Thank you very much for the opportunity to provide comments pertaining to the report. If we may be of further assistance to you in regard to this important issue, please feel free to contact us.

Sincerely,

Cynthia A. Schlick, MD, President
Minnesota Dermatological Society
Metropolitan Dermatology and Cutaneous Surgery, PA
1120 East Wayzata Boulevard, Suite 100
Wayzata, Minnesota 55391
952/476-6733

April 20, 2002 Jackie Harte
HTAC
121 E Seventh Place Suite 400
St. Paul, MN 55101

Dear Ms. Harte,

In response to HTAC report on tumescent responds as follows:

Page 1, lines 47-50: "While any physician can perform liposuction, board certification does not mean lone has the qualifications and experience to do the procedure. There are many non-accredited specialty boards that give certifications and make selecting a physician confusing for the public."

MSPS response: Yes, there are many non-accredited specialty boards; so called "bogus boards." However, board certification by the American Board of Plastic Surgery does mean one has the qualifications and experience to do the procedure. Liposuction continues to be the most common procedure performed by board certified plastic surgeons and the most common cosmetic procedure performed in plastic surgery training programs. Board certified plastic surgeons are fully trained in all aspects of plastic surgery and managing their complications. The American Board of Medical Specialties does recognize the American Board of Plastic Surgery.

The errors and omissions in the remainder of the report are numerous and many sources are non-scientific: "The Discovery Channel",), the South Florida Sun-Sentinel newspaper, the web site of SOBA (The Society of

Office Based Anesthesia), the South Florida Sun-Sentinel newspaper, etc...

The American Society of Plastic Surgeons deployed a special task force to address safety in liposuction and investigated the lidocaine toxicity and large volume liposuction. Appropriate guidelines were issued and there has not been a death from liposuction by a Board Certified Plastic Surgeon since these guidelines were initiated in 2001.

Board certified plastic surgeons are fully trained in all aspects of plastic surgery and managing their complications. Board Certified Plastic Surgeons are thoroughly trained in managing shock, sepsis, overwhelming infection etc: the rare, but serious complications that can occur after any type of liposuction. The American Board of Medical Specialties does recognize the American Board of Plastic Surgery.

Respectfully yours,

Mark Edward Lovaas, MD FACS
President
Minnesota Society of Plastic Surgeons

DERMATOLOGIC SURGERY

WILLIAM P. COLEMAN, III
EDITOR-IN-CHIEF

STUART SALASCHE, M.D.
CO-EDITOR

BARBARA TREGRE
MANAGING EDITOR\tab

\tab April 29, 2002

Ms. Jackie Harte
Project Team Leader
Health Technology Advisory Committee
121 East 7th Place, Suite 400
P.O. Box 64795
St. Paul, MN 55164-0975

Dear Ms. Harte:

I recently had the opportunity to review the HTAC report on tumescent liposuction. The report was well researched and quite good overall. However, since you quoted a number of references which I have authored, I thought it important to make two pertinent comments.

1. The report is not clear enough in differentiating tumescent liposuction and tumescent liposuction performed under general anesthesia. Tumescent liposuction was developed as a method for performing this procedure under local anesthesia. When general anesthesia is added to the tumescent liposuction technique there are increased complications.

Your report details many of these.

I would advise you to be more precise in your terminology and use the word tumescent liposuction to refer to liposuction done under local anesthesia. In cases where general anesthesia is used you should indicate so.

2. There is a significant error on page 9, line 13 where the report states that "advantages of general anesthesia for liposuction include minimal blood loss, low complication rate, and better regulation of fluid delivery." In fact, as many of the references you have cited have shown general anesthesia increases blood loss and increases complications when compared to local anesthesia for liposuction. This is also true for most other types of surgical procedures, as numerous studies have demonstrated.

   Thank you for the opportunity to comment on the HTAC Tumescent Liposuction Report. If you would like me to clarify any of my comments, please feel free to contact me.

Sincerely,

William P. Coleman, III, M.D.
Editor In Chief
Dermatologic Surgery

4425 Conlin Street, Metairie, LA 70006 * Telephone (504) 455-3180 - FAX (504) 885-2512

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For questions about this page, please contact our Health Policy, Information and Compliance Monitoring Division: hpsc@health.state.mn.us

See also > Health Policy, Information and Compliance Monitoring Division Home

Web Page Last Reviewed Tuesday, 12-Sep-2006 10:31:38 CDT