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Larger Infiltration/Aspiration Volumes, Plasma/ Subcutaneous Fluid Lidocaine Levels and Quantitative Abdominal Tissue Accommodation After Water-Assisted Liposuction (WAL): Comparative Safety and Efficacy to Traditional Liposuction (TL)

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1. Introduction

Traditional liposuction¹ remains a standard procedure for removal of unwanted fat. In contrast, water-assisted liposuction³⁴⁻³⁹(WAL), introduced in the United States less than three years ago, utilizes larger volumes of superwet tumescent anesthesia in small-moderate volume liposuction than that commonly employed by traditional liposuction (TL) in comparable cases. In larger infiltration-volume WAL cases, therefore, potential fluid overloading and lidocaine side-effects can occur as a consequence of technique. Thus, the first purpose of this preliminary report is to compare the infiltration and aspiration volumes, operating and recovery times, urine output rates in surgery and in the recovery period in larger infiltration-volume WAL cases to similar volume cases treated by traditional liposuction. The second purpose is to determine lidocaine levels in plasma and fluids within the subcutaneous space over 24 hours in a separate cohort of two patients undergoing larger-volume WAL procedures. The third purpose is to determine quantitatively by 3D Vector Analysis the significance of the WAL technique on percentages of tissue area reduction within panels on the lower abdomen in three separate patients.

2. Patient and methods

2.1 Study designs

All consented participants underwent either WAL or traditional liposuction procedures under local anesthesia by superwet tumescent infiltration and were offered preoperative oral sedation. An intravenous catheter was inserted in the arm as an access for drugs and intravenous fluid support during the entire surgical procedure and recovery period. The following demographic measurements were obtained prior to surgery: age, weight (kg), height (m), BMI, body fat analysis (Futrex 5500, Futrex Inc., Hagerstown, MD),

hematocrit/hemoglobin and blood chemistries Prior to surgery, patients were encouraged to drink electrolyte-containing fluids *ad libitum* and have a light protein breakfast.

In the first study, patients underwent larger volumes of infiltration by either WAL or traditional liposuction to their abdomens, back rolls, thighs, axillae and brachii to obtain data on 1) total infiltration/aspiration volumes, 2) total lidocaine dose (mg), total lidocaine dosage (mg/kg), and 3) hemodynamic stability and urine output. WAL uses a twochambered cannula that can independently either channel pulsations of tumescent solution (to loosen the fat and provide anesthesia) or spray pulses of tumescent fluid and simultaneously suction the rinsed, mobilized fatty tissue. Each WAL patient was treated in the three sequential stages. In Phase 1, pulses of tumescent solution [0.05% lidocaine (50ml of 1% lidocaine), 1:1,000,000 epinephrine (1ml of 1:1000 epinephrine), and 20ml 8.4% sodium bicarbonate per liter of 0.9% normal saline] were infused at the lowest rate of 90 ml/minute to provide localized anesthesia, vasoconstriction and tissue rinsing in a non-turgid manner to the planned site(s). During Phase 2, simultaneous suctioning (750mm Hg) and continuous pulsed infiltration, using a tumescent solution containing a reduced 0.025% lidocaine dose, evacuates the fatty tissue and a significant portion of the infusate. In Phase 3, a finishing cannula removes remnants of fatty tissue beneath the dermis with concurrent suctioning and lower rates of pulsed infiltration with 0.025% lidocaine solution. On the other hand, traditional liposuction patients were treated by superwet technique with the same tumescent solution, used in Phase 1 of WAL, prior to liposuction. Volumes (ml) and ratios of infiltration/aspiration/fat, lipocrits and urine output were calculated during and after surgery in the recovery room with each type of liposuction method.

In the second IRB study, two patients participated in the investigation of plasma and subcutaneous fluid lidocaine concentration levels, obtained over twenty-four hours during and after WAL abdominal liposuction, to determine the time and magnitude of peak values. In addition, total infiltration/aspiration volumes, total lidocaine dosage (mg), total lidocaine dosage (mg/kg), and urine output were recorded. Lidocaine concentration levels of plasma and fluid within the subcutaneous space were measured by the Emit 2000 Lidocaine Assay (Dade Behring, Inc., Cupertino, CA), a homogeneous enzyme immunoassay technique, based on competition between drug in the sample and drug labeled with recombinant glucose-6-phosphate dehydrogenase for antibody binding sites. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change measured by spectrophotometric analysis.

In the third study (IRB, controlled, randomized), three patients received randomly assigned treatments of three cumulative phases of a WAL procedure within 4 x 10cm rectangles on their abdomens, with an additional control panel, listed in Table 1. Standardized photography, weight, body fat analyses, waist and hip circumferences were obtained at baseline and three months after treatment. Tissue reduction was assessed by using the Vectra 3D Software System (Canfield Scientific, Fairfield, NJ), that identified the permanent India ink markers around corners of each targeted site and calculated changes in horizontal, diagonal and perimeter baseline measurements compared to findings at three months. At the completion of the study, total abdominal liposuction was performed on each subject to achieve a final aesthetic result.

Results

Study 1. As shown in Table 2, twelve WAL patients (8 females; 4 males) with an ASA I classification underwent large infiltration volume and fat aspiration. Participants averaged a

mean age of 49.0 years (range 29-61 years), mean weight of 71.1kg (range 51.7-98.9 kg), mean height of 1.7 meters (range 1.3-1.9 meters), mean body mass index of 25.2 (range 21.0 -30.2), and mean body fat of 31.9% (range 23.0-35.0%). As summarized in Table 3, thirteen TL patients (10 females; 3 males) with an ASA I classification underwent large infiltration volume and fat aspiration. This group of patients averaged a mean age of 53.3 years (range 32-63 years), mean weight of 77.5kg (range 67.1-94.3kg), mean height of 1.7 meters (range 1.5-1.9 meters), mean body mass index of 27.4 (range 24.0-30.3), and mean body fat of 33.7% (range 27.8-36.4%).

Panel	Treatment Assignment
1	Control
2	Phase 1: Infiltration Solution (25ml) (25 cannula passes)
3	Phase 1: Infiltration Solution (25ml) (25 cannula passes) Phase 2: Simultaneous Suctioning (100ml) and Infiltration (225ml) (25 cannula passes)
4	Phase 1: 25ml Infiltration Solution (25 cannula passes) Phase 2: Simultaneous Suctioning (100ml) and Infiltration (225ml) (25 cannula passes) Phase 3: Simultaneous Suctioning (25ml) and Infiltration (50ml) (10 cannula passes)

Table 1. Target Zones and Treatments

WAL patients received almost all their total fluid support from infiltration solutions which served as their anesthetic solution, maintenance fluid, and volume replacement fluid (Table 2). The average total subcutaneous infiltration volume was measured at 6239ml (range 4920-7500ml), while the average aspiration volume was calculated at 5460ml (range 4350-6900ml). The average infiltration-to-aspiration ratio was 1.2:1 (range 1.1:1-1.3:1). The average volume of aspirated fat was 2456ml (range 1716-3105ml), which calculated to an average infiltration-to-fat ratio of 2.6:1 (range 2.2:1-3.0:1) and an average fat-to-aspirate percentage of 44.9% (range 37.6-56.2%). During surgery, patients received an average total lidocaine dose of 1702mgs (range 1423-2095mgs) and an average lidocaine dosage of 24.2mg/kg (range 18.9-33.6mg/kg)

In contrast, TL patients received their total fluid support both from the infiltration tumescent solution and intravenous saline fluid resuscitation (Table 3). The average total subcutaneous infiltration volume was measured as 5350ml (range 4500-6500ml), while the average aspiration volume was calculated at 5042ml (range 4000-6000ml). The average infiltration-to-aspiration ratio was 1.1:1 (range 1.0:1-1.1:1). The average volume of aspirated fat was 4036ml (range 3280-4800ml), which calculated to an average infiltration-to-fat ratio of 1.3:1 (range 1.2-1.6) and an average fat-to-aspirate percentage of 80.2% (range 70.0-86.0%). During surgery, patients received an average total lidocaine dose of 2675mg (range 2450-3100mg) and an average lidocaine dosage of 34.8mg/kg (range 27.0-40.9mg/kg).

		T 4.7.	T.T.		Total	Lido	Total	Total	T / A	Total	L/E	T ()
Pt #	Pt # Age	Wt (kg)	Ht	BMI	Lido	Dosage	Infiltratio	Aspiratio	I/A Patio*	Fat	I/F Patio**	F/A
			(m)		(mg)	(mg/kg)	n (ml)	n(ml)	Ratio*	(ml)	Ratio**	(%)
1	29	97.5	1.8	30.2	1690	17.3	5760	4900	1.2:1	2500	2.3:1	51.0
2	44	51.7	1.7	23.0	1735	33.6	5940	4700	1.3:1	2021	2.9:1	43.0
3	61	54.0	1.5	21.8	1480	27.4	4920	4400	1.1:1	1716	2.9:1	39.0
4	57	56.2	1.3	23.4	1550	27.6	5200	4812	1.1:1	2117	2.4:1	44.0
5	42	92.5	1.7	28.0	2095	22.6	7375	6900	1.1:1	3105	2.4:1	45.0
6	60	98.9	1.9	28.0	1600	16.2	5400	4350	1.2:1	1783	3.0:1	41.0
7	55	70.3	1.7	23.5	1767	25.1	7000	6885	1.0:1	2592	2.7:1	37.6
8	45	67.0	1.6	27.1	1833	27.5	7500	6550	1.1:1	3050	2.4:1	46.5
9	44	63.5	1.6	25.8	1684	26.5	6550	5575	1.2:1	2174	3.0:1	39.0
10	46	52.0	1.6	21.0	1423	18.9	6050	5550	1.1:1	2775	2.2:1	50.0
11	56	82.5	1.8	27.0	1767	21.4	6600	5375	1.2:1	3020	2.2:1	56.2
12	49	66.8	1.7	23.3	1800	26.9	6575	5525	1.2:1	2630	2.5:1	47.6
Avg.	49	71.1	1.7	25.2	1702	24.2	6239	5460	1.2:1	2456	2.6:1	44.9

* Infiltration-to-Aspiration Ratio ** Infiltration-to-Fat-Ratio

Table 2. Demographic and Clinical Data in Twelve Patients for Larger Volume Water-Assisted Liposuction

Pt #	Age	Wt (kg)	Ht (m)	BMI	Total Lido (mg)	Lido Dosage (mg/kg)	Total Infiltration (ml)	Total Aspiration (ml)	I/A Ratio*	Total Fat (ml)	I/F Ratio**	F/A (%)
1	61	74.8	1.7	26.0	2750	36.8	5500	5200	1.1:1	4108	1.3:1	79.0
2	53	73.4	1.5	26.0	3000	40.8	6000	5500	1.1:1	3850	1.6:1	70.0
3	37	81.6	1.7	28.2	2625	32.4	5250	5000	1.1:1	4050	1.3:1	81.0
4	68	92.9	1.9	26.5	2600	27.9	5200	4990	1.0:1	4142	1.2:1	83.0
5	63	79.3	1.6	28.0	3250	40.9	6500	6000	1.1:1	4740	1.4:1	79.0
6	62	78.4	1.6	29.2	3100	39.5	6200	6000	1.0:1	4800	1.3:1	80.0
7	49	72.5	1.6	25.2	2500	34.4	5000	4950	1.0:1	3811	1.3:1	76.9
8	32	74.8	1.6	30.3	2250	30.1	4500	4000	1.1:1	3280	7 1.4:1	82.0
9	53	67.1	1.5	28.0	2650	39.5	5300	5000	1.1:1	4150	1.3:1	83.0
10	62	94.3	1.8	29.0	2550	27.0	5100	5000	1.0:1	3900	1.3:1	78.0
11	49	74.8	1.7	26.0	2500	33.4	5000	4900	1.0:1	4214	1.2:1	86.0
12	49	70.4	1.5	29.0	2450	35.1	4900	4500	1.1:1	3645	1.3:1	81.0
13	55	72.7	1.6	24.0	2550	34.8	5100	4500	1.1:1	3780	1.3:1	84.0
Avg	53.3	77.5	1.7	27.4	2675	34.8	5350	5042	1.1:1	4036	1.3:1	80.2

*Infiltration-to-Aspiration Ratio **Infiltration-to-Fat Ratio

Table 3. Demographic and Clinical Data in Thirteen Patients for Larger Volume Traditional Liposuction

The average operating time for the larger volume WAL group was 4.0 hours (range 3.0-5.0 hours), while the average time in the recovery room was 1.4 hours (Table 4). The average tumescent infiltration fluid rate was 24.8ml/kg/hr (range 13.1-38.8 ml/kg/hr). The average urine output in surgery was 1.8 ml/kg/hr (range 1.3-2.5 ml/kg/hr), while the average urine output in the recovery room was 2.2ml/kg/hr (range 1.5-2.7ml/kg/hr). As cited in Table 5, similar data was obtained from the larger volume TL patients who demonstrated an average operating time of 3.5 hours (range 3.0-4.0 hours) and an average recovery time of 1.3 hours (range 1.0-1.5 hours). The average tumescent infiltration fluid rate during surgery was 20.4ml/kg/hr (range 15.5-27.0ml/kg/hr). The average urine output in surgery was 2.0ml/kg/hr (range 1.3-2.7ml/kg/hr), while the average urine output in the recovery room was 2.1mlkg/hr (range 1.7-2.4ml/kg/hr). The majority of patients were monitored for over 12 hours after surgery.

Pt #	OR	Recovery	Infiltration Fluid	Urine Output Rate	Recovery Room Urine
	Time	Time OR	Rate (ml/kg/hr)	(ml/kg/hr)	Output
	(hrs)	(hrs)	During Surgery	During Surgery	(ml/kg/hr)
1	4.5	1.5	13.1	1.3	1.2
2	3.0	1.5	18.4	1.8	1.7
3	3.0	1.25	16.8	1.7	1.5
4	4.0	1.5	11.9	1.3	1.2
5	3.0	1.5	11.7	2.0	1.2
6	3.5	1.5	15.2	1.3	1.3
7	5.0	1.5	19.9	2.1	2.5
8	4.0	1.0	28.0	1.7	2.0
9	3.5	1.2	29.5	1.5	2.2
10	3.0	1.5	38.8	1.8	2.3
11	5.0	1.5	16.0	2.5	2.7
12	5.0	1.0	19.7	2.2	2.4
Avg.	4.0	-1.4	24.8	1.8	2.2

Table 4. Operating/Recovery Times, Infiltration Fluid Rates and Urine Output Rates in Larger Volume Water-Assisted Liposuction

In both WAL and TL groups, lipocrits of less than 1.0% were estimated from millimeters of red blood cell presence and millimeters of non-red blood cell containing fluid from aspirates measured within centrifuged capillary tubes from final aspirates in each patient. Preoperative hematocrit, hemoglobin, electrolytes, blood urea nitrogen/creatinine and liver function test levels demonstrated no significant changes from their 3-month postoperative values. During surgery and the perioperative period, episodes of tachycardia, hypotension, excessive bleeding, dyspnea/wheezing, significant detectable fluid shifts, pulmonary edema, congestive heart failure, or low urine output were not observed. Each patient was assessed to be stable hemodynamically throughout the entire procedure and in the recovery period.

None of the TL or WAL patients developed in the immediate postoperative period or after 6-month follow-ups infections, deep venous thrombosis or skin loss. Subjective assessments of postoperative pain suggest that WAL patients on an individual basis experienced less pain and discomfort and were able to resume normal pre-surgical activities more rapidly than TL patients. There were no significant differences in the low incidences of ecchymoses, surface irregularities and nodular fibroses between the two treatment groups.

				\frown		
Pt. #	OR	Recovery	Parenteral and Infiltration	Fluid Urine Output	Recovery Room	
	Time	Time OR	Rate (ml/kg/hr)	Rate (ml/kg/hr)	Output	
	(Hrs)	(Hrs)	During Surgery	During Surgery	(ml/kg/hr)	
1	3.5	1.5	20.9	2.3	2.2	
2	3.0	1.5	27.0	2.0	2.4	
3	3.0	1.0	21.3	2.5	2.1	
4	2.5	1.5	22.4	2.6	2.3	
5	4.0	1.0	20.6	2.7	2.0	
6	3.5	1.0	22.0	1.9	2.0	
7	4.0	1.0	17.2	1.5	1.7	
8	4.0	1.5	15.0	1.3	1.5	
9	4.0	1.5	19.8	2.1	2.4	
10	3.5	1.0	15.5	2.0	2.2	
11	3.0	1.0	22.3	1.7	1.9	
12	3.0	1.5	23.2	1.5	2.0	
13	4.0	1.5	17.5	1.9	2.2	
Avg	3.5	1.3	20.4	2.0	2.1	

Table 5. Operating/Recovery Time, Infiltration Fluid, Rates and Urine Output Rates in Larger Volume Traditional Liposuction

Study 2. Two female subjects with an ASA I classification volunteered for lidocaine levels in plasma and fluid within the subcutaneous space during and after liposuction of their abdomens. The following demographic measurements from subject 1 and subject 2 were obtained, respectfully: age (33yr, 47yr), height (1.7m, 1.6m), weight (78.6Kg, 59.0Kg), body fat (38.3%, 36.0%), and BMI (27.2, 23.9). For each respective subject, the total tumescent infiltration volumes (5900ml, 3050ml), final aspiration volumes (5500ml= 750ml fat + 4750ml infranate); 3050ml = 575ml fat + 1875ml infranate), total lidocaine doses (1700mg, 975mg), and lidocaine dosages (29.5mg/kg, 12.5mg/kg₂) were tabulated. In subject 1, the average tumescent infiltration fluid rate was 25.0ml/kg/hr, while the average urine output during surgery and in the recovery room was 1.5ml/kg/hr. In subject 2, the average tumescent infiltration fluid rate was 17.2ml/kg/hr, while the total urine output was 2.1ml/kg/hr. Serial lipocrits were calculated less than 1.0% of infranates collected from each subject. Preoperative blood work demonstrated no significant changes from 3 month post-operative values. During surgery and postoperative recovery period (average 3 hours), subjects did not exhibit any deleterious signs or symptoms that could be attributed to lidocaine toxicity or fluid overload. Patients received no parenteral fluid support other than tumescent infiltration and were observed to be hemodynamically stable throughout the office procedure and continued recovery at home.

Lidocaine concentrations in plasma and fluids with the subcutaneous space were measured by enzyme immunoassay technique and plotted by connecting the sequential levels for a continuous curve over 24 hours (Figure 1). The peak occurrence of the peak plasma lidocaine concentration, were observed at about 9 hours in both subjects. At 30 minutes, elevated plasma levels were measured at $0.5-0.1\mu g/ml$, gradually rising to peak levels between $0.80-0.95\mu g/ml$, and falling to $0.30\mu g/ml$ at 24 hours. All recorded plasma levels were lower than elevated levels from subcutaneous fluids within the tumescent-treated abdomens measured between $1-1\frac{1}{2}$ hours (95-130ug/ml) and after 6-8 hours (66-95 $\mu g/ml$) from the start of lidocaine infiltration.

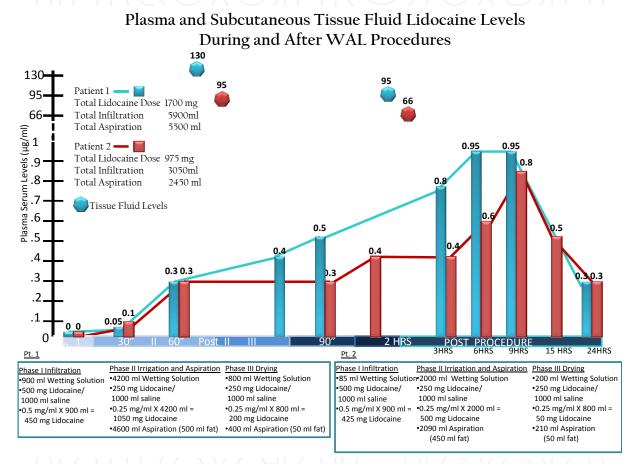


Fig. 1. Serial lidocaine levels in plasma and fluid within subcutaneous space during and after WAL procedures.

Study 3. Three female patients with ASA I classifications had an average age of 46 years (range 26-66 years). Each patient's pretreatment weight, percent body fat, BMI, and hip circumference did not vary significantly from the measurements 3 months after surgery. In each subject, a reduction in waist circumference from baseline to 3 months was observed (Table 6).

Results of surface area changes from baseline to 3 months within the four isolated rectangles, as determined by Vectra 3D analysis, are shown in Figure 2. Each target panel received cumulative components of the standard treatment protocol for a WAL procedure. At the three month evaluation period, the difference in mean percent area of tissue reduction between panel 1 (control) and panel 2 (subcutaneous infiltration) was negligible.

However, the increases in mean percent area of tissue reduction, observed in panel 3 (6.8%) and in panel 4 (6.7%) over control (0.0%) and panel 1 (1.2%), indicate that the removal of fat facilitates increased the accommodation, retraction or contraction of the overlying skin.

Pt	Weight (kg)		% Body Fat		Body Mass		Waist		Hip Circum.	
#				-	Index		Circum.(cm)		(cm)	
	0	3	0	3	0	3	0	3	0	3
	mos	mos	mos	mos	mos	mos	mos	mos	mos	mos
1	67.3	68.6	40.8	42.6	26.2	26.8	94.5	92.0	106.0	106.0
2	79.5	79.1	38.1	37.5	25.9	25.8	109.5	105.0	108.0	107.5
3	83.6	83.2	39.6	40.5	30.7	30.5	105.0	101.0	107.0	106.0

Table 6. Patient Demographics in Abdominal Tissue Tightening Study

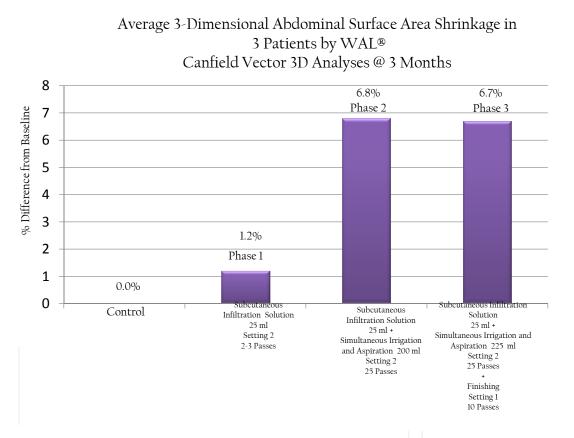


Fig. 2. Average 3-Dimensional Abdominal Surface Area Reduction in 3 Patients by Treatment Phases of WAL by Canfield Vector 3D Analyses at 3 Months.

3. Discussion

Traditional liposuction continues to be the gold standard to remove fat and contour body shapes. Since 1986, advocates preferred either a superwet^{9,15-17,28-31} or a tumescent technique^{2-8,10}, each of which have established proven safety and efficacy profiles using similar anesthetic solutions, but with significantly differing ratios of infiltration volume to total aspiration volumes. Each technique appears to be safe when strict clinical criteria¹¹⁻¹⁴ are

observed such as selecting ASA I patients, using less than 5 liters of dilute volumes of lidocaine and epinephrine for average cases, limiting total lipoaspirates to less than 5 liters in the outpatient setting, respecting the safe maximum 35mg/kg of lidocaine, and prolonging patient discharge for large volume cases because of various factors delaying peak lidocaine levels as late as 10 to 15 hours. In particular, safer outcomes have been reported when the physiologic impact of larger volume liposuction is understood in cases that are associated with significant fluid shifts, third space losses, and potential epinephrine and lidocaine side-effects and toxicities.

In larger cases, superwet technique²⁸⁻³¹ is usually associated with the use of parenteral fluid maintenance and replacement with total intravenous or general anesthesia, while Klein's tumescent technique^{6-7, 10} recommends the elimination for parenteral fluid support or total intravenous/general anesthesia in large volume cases. With either technique, however, the issue of absorption of the tumescent fluid infiltrate is complicated by the removal of the infiltrate along with fat and blood during suctioning. Since most of the infiltrate, ranging from 22-29 percent, is not removed by suctioning, at least 70 percent of the infiltrate is believed to remain after the procedure^{20, 49}. Fluid overload^{28, 33, 41, 51-53} becomes possible whenever substantial amounts of tumescent infiltrative fluids or parenteral fluids are used in high volume cases with the tumescent (3-4:1 ratio) and superwet (1-1.5:1) techniques. Since WAL's variable force infusion pump pulses fan-shaped jets of tumescent solution into the subcutaneous fatty tissue during its three procedural phases, but only suctions simultaneously the loosened fat and fluid during the latter two phases, the final physiological and pharmacological impact is expected to reflect more closely the infiltrationto-aspiration ratios (between 3-4:1) observed with the tumescent technique. The author's recent WAL publication³⁹ provided, however, evidence to the contrary by recording an average 1.1:1 infiltration to aspiration ratio in fifty small-moderate infiltration volume cases. Although the present study 1 data was underpowered for statistical significance, the observed results indicated that WAL and TL exhibited a comparative safety margin in similar types of cases for larger volumes of infiltrated tumescent solution, lipoaspiration, and fat removal, respectfully: average total infiltration (WAL, 6239ml; TL, 5350ml); total aspiration (WAL, 5460ml; TL, 5042ml, and total fat (WAL, 2456ml; TL, 4036ml). In these cases, the average calculated infiltration-to-aspiration ratios were similar (WAL, 1.2:1; TL, 1.1:1), approaching that observed in typical cases using superwet technique (1-1.5:1) rather than that experienced with the Klein tumescent technique (3-4:1). Although explanations for WAL's findings as a superwet technique are unclear, the data suggest that simultaneous infiltration- aspiration for the greater part of the procedure in phases 2 and 3 may account for the observed balanced I/A ratio, as found with TL procedures. In this study, the use of WAL, however, resulted in a

lower average fat-to-aspiration ratio (44.9%) than that observed with TL (80.2%) or with other devices^{17, 19-21, 42, 46, 54} that commonly experience 70-90% fat-to-aspiration ratios in comparable volume cases. These findings suggest that WAL may be more inefficient in removing more fibrous fat from the back rolls and upper abdomen than TL.

In this study, the average total lidocaine dose was larger in TL patients (2675mg) than in WAL patients(1702mg) because of higher concentrations delivered during the entire procedure in TL patients (0.05% lidocaine, average 5350ml total tumescent infiltration) than in WAL patients (phase 1, 0.05%; phases 2-3, 0.025% lidocaine, average 6239ml total tumescent infiltration). For similar reasons, the lidocaine dosage exposure was greater in the TL patients (34.8mg/kg) than in WAL patients (24.2mg/kg).

Although the average tumescent fluid infiltration volume (24.8ml/kg/hr) in the WAL patients provided the only fluid replacement, urine output safely averaged about 1.8 ml/kg/hr during surgery and 2.2ml/kg/hr in the postoperative recovery period. In the TL patients, the average tumescent fluid infiltration volume (5350ml) was augmented by parenteral intravenous fluid support (average 1000ml ringer's lactate) for a total infiltration fluid rate of 20.4ml/kg/hr during surgery to maintain an average urine output rate of 2.0ml/kg/hr in surgery and 2.1ml/kg/hr in the recovery room. In both procedures, clinical parameters of fluid overload (pulmonary edema, dyspnea, wheezing, congestive heart failure), low maintenance fluid replacement (tachycardia, hypotension, low urine output), and significant blood loss attributable to the procedure were not observed. In larger infiltration volume WAL or TL cases, however, patients must be provided with an available intravenous access site, be the recipient of prewarmed tumescent fluids, supported by a warming blanket and an anti-embolic calf/ankle pumps, and monitored fluid outputs with a urinary catheter. The information from this limited comparison of techniques does not significantly add to previously published data^{4, 6,10,15,50}, but confirms the safety profile during larger infiltration and liposuction cases under local anesthesia. Along with sound clinical judgment, both techniques may be performed safely under strict preoperative criteria, intraoperative fluid monitoring, and postoperative assessments for at least 12 hours. Overnight stays are recommended for monitoring of vital signs and fluid resuscitation in larger volume cases.

The pharmacokinetics of dilute amounts of lidocaine^{4, 6, 21}, approaching 35mg/kg, and epinephrine into subcutaneous fat with relatively large volumes of fluid have been found to be safe with the tumescent technique because of slow absorption of lidocaine in the presence of epinephrine, poor vascularity of fatty tissue, and the removal of a variable amount of much of the infused lidocaine by suction before systemic absorption. In studies^{21-27, 55} associated with high dosages, peak serum levels below toxic levels of 5µg/ml were measured about 10-12 hours after infiltration. In the second part of this study, the lidocaine dosages used in the two patients were calculated at 12.5mg/kg and 29.5mg/kg, exceeding the recommended the safe limit of lidocaine dosage of 7mg/kg with epinephrine in normal healthy adults^{31,40}, but below the estimated maximal safe dosage of 35mg/kg, as recommended in the Klein tumescent technique¹². The low plasma peak levels between 0.80- 0.95μ g/ml at 9 hours and the elevated subcutaneous fluid levels from lipoaspirates at 1-1 $\frac{1}{2}$ hours (95-130µg/ml) and after 6-8 hours (66-95µg/ml) from the start of lidocaine infiltration were consistent and similar with those observed in previous cited publications. These results confirm the relative safeness of using larger infiltration volumes with simultaneous liposuction during the WAL technique. Because of costs, the study was limited to few patients and used an enzyme immunoassay technique that was unable to measure the variability in protein binding and active metabolites of lidocaine (monoethylglycinexylide and glycinexylidide)³², which can be over 80% active and contribute to lidocaine toxicity. Although no significant side effects have been reported with higher lidocaine dosages^{33, 55}, further expanded clinical and laboratory studies need to be performed to determine the optimal lidocaine dose for WAL to provide complete local anesthesia.

Although the number of patients in third part of the study is small for statistical significance, the observed results indicated tissue accommodation after WAL treatments. In younger patients who present with minimal laxity to the overlying skin, the removal of fat

can be expected to result in normal skin retraction, as observed in panels 3 and 4. There exists no evidence from this study that this beneficial finding was due to the preservation of the septal architecture. In the future, one of the challenges for WAL, as with other energized liposuction devices⁴²⁻⁴⁷, is to investigate the contribution of energy in the form of mechanical or thermal injury to improve tissue reduction/contraction in the skin-challenged patient. Their limited clinical benefit brings into perspective the cost-benefit value of thermally-equipped devices for tissue tightening and emphasizes the need for further clinical research and applications⁴⁸.

In conclusion, we believe that larger-volume liposuction is safe and efficacious by WAL compared to TL, provided attention is directed to tumescent anesthesia, fluid replacement and overload, blood loss and postoperative monitoring for potential lidocaine side-effects.

4. Conclusions

On the basis of our limited and preliminary study, patients undergoing WAL procedures, as well as TL procedures, are safe for cases involving larger infiltration/aspiration volumes that introduce the possibility of lidocaine side-effects and toxicities and fluid imbalance. Patients did not experience significant adverse events in this study. Specifically, this brief study demonstrated that current algorithm with WAL treatments results in peak plasma lidocaine levels between 0.80-0.95ug/ml around 9 hours when subcutaneous fluid levels were elevated around 95-130ug/ml at $1-1\frac{1}{2}$ into surgery and $66-95\mu$ g/ml at 6-8 hour after lidocaine infiltration. Although the correlation between total plasma lidocaine concentration ($<5\mu$ g/ml) and the predictability of specific toxicity is tenuous at best and can lead to false sense of security, the surgeon must always be mindful of careful clinical monitoring during and at least 24 hours after completion of the procedure. In addition, preliminary results, indicating a small but positive trend for skin reduction by Vectra 3D analysis, remain underpowered for significance and will require larger number of patients for statistical validation.

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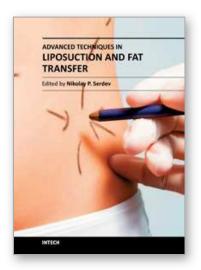
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