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ORIGINAL RESEARCH REGIONAL ANESTHESIA

Conventional versus diluted spinal anesthesia for lower limb tumescent liposuction: a randomized clinical trial

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ABSTRACT

Background & Objectives: Liposuction is being increasingly done as a daycare procedure under spinal anesthesia. The aim of daycare surgery is to have fast recovery of psychomotor and cognitive functions, that allow early discharge of the patients. This study was done to compare conventional versus diluted spinal anesthesia in lower limb liposuction procedures in terms of time to discharge, patient satisfaction and redo rate.

Methodology: We recruited 108 female patients, and randomly allocated them into either a conventional spinal group (Group CS), that received 15 mg of bupivacaine or a diluted spinal group (Group DS) that received a diluted 7.5 mg bupivacaine. All patients underwent tumescent liposuction. The primary outcome was to assess time to home readiness and secondary outcome was patient satisfaction, the incidence of complications and the redo rate. Data were analyzed by analysis of variance test, Student's t-test, Whitney U test and Chi-square tests. $P < 0.05$ was taken as statistically significant.

Results: The Group DS was found to have a significantly less duration of hospital stay (216.89 ± 34.99 min) as compared to Group CS (302.23 ± 22.35 min) ($P < 0.001$). Patients in DS group were found to have a significantly high satisfaction score as compared to Group CS ($P < 0.001$). Overall Incidence of complications was found to be less in Group DS as compared to Group CS ($P < 0.001$).

Conclusion: The use of a diluted, lower dosage of bupivacaine intrathecally provides early discharge with satisfactory anesthesia in lower limb liposuction procedures. The complication and redo rates were also significantly less with the use of diluted bupivacaine for spinal anesthesia.

Keywords: Lower limb liposuction; Bupivacaine; Discharge time; Patient satisfaction; Complications

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1. INTRODUCTION

With rapid urbanization and sedentary life style the world is staring at a pandemic of obesity with consequent increase in surgeries such as liposuction. It is being increasing done for medical as well as aesthetic considerations.[1] Earlier liposuction was frequently done under general anesthesia however

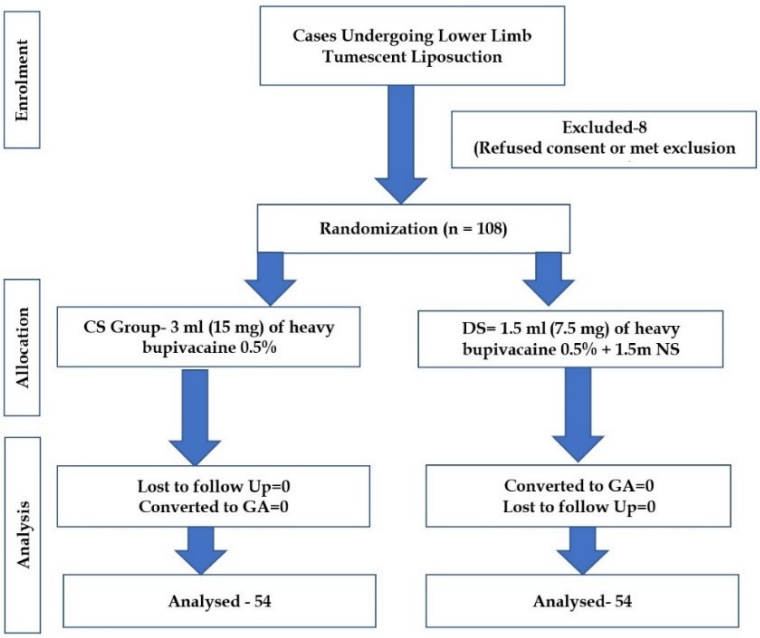

Figure 1 : Flow Diagram of Cases Enrolled on the basis of predefined Inclusion and Exclusion Criteria

general anesthesia was found to be associated with unacceptably high risk of morbidity as well as mortality. For this reason, nowadays these surgeries are frequently being done as a day care procedure under spinal or local anesthesia[2].

Liposuction under local or spinal anesthesia is associated with reduced hospital stay as well as morbidity and mortality as compared to liposuction done under general anesthesia.[3] Although local anesthesia is preferred by some surgeons to reduce costs, it has a brief duration, does not provide adequate anesthesia due to non-uniform distribution of injected local anesthetics, and so deep sedation is required with its risks.[4] General anesthesia is another option; but it carries the risks of airway instrumentation, increased incidence of nausea and vomiting, as well as loss of patient communication. Epidural block also can be useful but its technique is difficult relative to subarachnoid block , need special set and skills and carry higher risk than spinal anesthesia, on the same time, it will be more suitable for long procedures, Subarachnoid block is a useful technique for liposuction below the umbilical area, it is safe, low cost, keep patient communication, with few side effects.[5]

The use of a low dose diluted spinal anesthetic, may reduce the intensity of the motor block and the duration of spinal anesthesia, enabling an earlier discharge.[6] Usually the position for most of liposuction procedures is supine, however, this position will differ according to the area of liposuction; buttocks and back of the thighs requires prone position and appropriate precautions should be taken to avoid pressure injuries.[7]

To our knowledge there is no other randomized clinical trial which dealt with the use of a low dose, diluted spinal anesthetic during liposuction of the lower extremities. We hypothesized that use of a low dose, diluted spinal anesthetic with the help of tumescent local anesthetic solution, would provide adequate anesthesia, accelerate recovery and the time to discharge for patients undergoing tumescent liposuction of the lower limb. Moreover, this technique would lead to an increased stability of patient hemodynamics which facilitate patient movement during the procedure in order to intraoperative assess the suctioned areas and decrease the probability of a repeat procedure.

2. METHODOLOGY

The present study was a prospective, randomized clinical study approved by the Ethics Committee of Menoufia University Hospital in Egypt. Written informed consent was obtained from all participants.

108 female patients, American Society of Anesthesiologists physical status I–II, aged 18–50 years with body mass indices <35, scheduled for lower extremity tumescence liposuction were enrolled in this study. Exclusion criteria included patients' refusal to participate, severe cardiovascular, respiratory or coagulation abnormalities or infection at injection sites.

Randomization was performed using a computer-generated program through which patients were assigned to two equal, parallel groups: either a conventional spinal (CS) group or a low dose, diluted spinal (DS) group. The patients, anesthetists, and outcome assessors were all blinded, only anesthesia technician was aware and kept the key codes confidential until the end of the study.

For each patient, a 20-gauge intravenous cannula was inserted. All patients were preloaded with 500 mL of warmed lactated ringer. Patients were monitored using electrocardiography, noninvasive blood pressure monitoring, pulse oximetry, and axillary temperature was monitored by AccuSure® Digital Thermometer (MT-1027) (Microgene®). The baseline vitals were recorded.

Patients were assisted into the sitting position. Spinal anesthesia was performed with a 27-gauge sharp cutting needle, and the appropriate anesthetic drug was injected via sterile syringes at L3−4 or L4− 5 intervertebral space. The Group CS received 3 mL (15 mg) of heavy bupivacaine 0.5%, and the DS group

Table 1: Demographic details, duration of surgery and volumes of tumescent mixture and suctioned lipid emulsion.

Parameter	Groups		*t*-test	P-value
	CS (N = 54)	DS (N = 54)		
Age (y)	35.44 ± 6.27	37.70 ± 7.15	0.066	0.086
BMI (kg/m^2)	30.26 ± 3.89	31.15 ± 3.24	3.840	0.202
Duration of operation (min)	90.35 ± 12.08	93.54 ± 11.48	0.116	0.167
Axillary temperature (°C)	36.17 ± 0.72	36.71 ± 0.42	3.828	0.110
Respiratory rate (breaths/min)	14.69 ± 2.44	14.78 ± 2.04	0.875	0.845
Oxygen saturation (%)	98.42 ± 2.32	98.56 ± 1.21	0.413	0.715
Tumescent mixture injected (L)	3.43 ± 0.60	3.53 ± 0.64	0.005	0.398
Volume of lipid emulsion suctioned (L)	3.83 ± 0.56	3.67 ± 0.59	0.070	0.155

Data presented as mean ± SD

received 1.5 mL (7.5 mg) of heavy bupivacaine 0.5% diluted to 3 mL by adding 1.5 mL of sterile normal

saline. Patients were then instructed to lie. The level of the sensory block and the motor block was assessed, then the surgeon was permitted to start the warmed tumescent mixture injection (each liter of normal saline containing 50 mL of lidocaine 2%, 1 gram of epinephrine, and 12.5 mmol of sodium bicarbonate) injected into the subcutaneous tissue to make it firm, swollen, and rigid. All required areas were injected in sequence, number of litres of saline with tumescent injection not exceeding the calculated lidocaine dose for each patient (50 mg/kg).

After injection, the surgeon used VASER (vibration amplification of sound energy at resonance) ultrasound waves to break down the fat and liquify it for easy suction and better contouring results,

Liquification and suction started with the same sequence of injection, after 60–90 min patients were requested to move with assistance to evaluate the result after suction.

The primary aim was to compare the time to discharge between the groups, [the time elapsed from the start of the spinal injection to the time at which the patient left the hospital]. Secondary outcomes were the assessment of patient hemodynamics, such as heart rate, mean arterial blood pressure (ABP), SpO_2, and axillary temperature were recorded every 5 min for the first hour, then every 15 min during the procedure and in the Post Anesthesia Care Unit (PACU). The time to maximum sensory block level was noted by pinprick testing, and motor block by using the modified Bromage scale[8] [0 = no motor block, 1 = inability to raise the extended leg but able to bend knees and move feet, 2 = inability to raise the extended leg or to bend the knees but able to move feet, and 3 = complete motor block of the lower limbs]. Sedation requirement (midazolam 2–5 mg) specially during VASER was also compared. Time of voiding urine after motor recovery, ability to move with assistance, degree of patient satisfaction (just before discharge), motor recovery time, surgeons satisfaction score and first request for analgesia were compared between 2 groups. Diclofenac sodium 75 mg intramuscularly and paracetamol 1g were used once the patient started to feel little discomfort in suction areas.

Incidence of complications as signs of local anesthesia toxicity, volume overload, were observed and recorded. Bradycardia (heart rate <50 beat/min) was treated by 0.5 mg atropine. Hypotension (>20% decrease in mean ABP), was treated by increasing hydration, with or without 3 mg ephedrine. Incidence of nausea and vomiting was recorded throughout the operation and recovery time. Shivering was recorded throughout the procedure and recovery time. Incidence of headache and backache were recorded in the first one week after anesthesia and compared between groups.

Statistical analysis

Power analysis was performed using the G-power 3.1.9 program. Sample size calculations were conducted based on our pilot studies, given an effect size of a 50% reduction in the time to discharge (the difference between the groups means), with a power of 80% and an alpha error of 0.05%, which yielded a required total sample size of 102 (51 per group). The total sample size was increased to 108 to avoid sample dropouts due to possible exclusions.

Results were statistically analyzed by version 20 (SPSS Inc., Chicago, IL, USA). The Student's *t*-test was used for analysis of parametric data, while the Mann-Whitney *U* test was used for nonparametric data. The chi-squared (χ^2) and Fisher's exact tests were used for qualitative variables. $P < 0.05$ was considered statistically significant.

3. RESULTS

The patients were compared on the basis of demographic profile, BMI, oxygen saturation,

Table 2: Comparison of sensory and motor blockade, time to maximum sensory block level, voiding time and time of discharge in studied cases

Parameter	Group CS (N = 54)	Group DS (N = 54)		P-value
Highest level of sensory block (Modified Bromage scale)				
• 3	43 (79.63)	12 (22.2)	38.166**	< 0.001*
• 2	11 ((20.37)	32 (59.3)		
• 1	0 (0.0)	10 (19.4)		
Time to maximum sensory block level (min)	7.42 ± 1.51	7.78 ± 1.7	0.479 ***	0.259
Voiding time (min)	302.23 ± 22.35	158.52 ± 24.97	0.738 ***	< 0.001*
Time to discharge (min)	353.81 ± 24.59	216.89 ± 34.99	8.557 ***	< 0.001*

*Data presented as n (%) or mean ± SD; ** Chi-squared test; *** t-test; *P < 0.05 considered as significant*

duration of surgery and volume of tumescent mixture as well as lipid emulsion suctioned. All these parameters were found to be comparable in both the groups with no statistically significant difference in any of these parameters (P > 0.05) (Table 1).

Patients were compared on the basis of first request of analgesia after surgery, intraoperative requirement of sedation and ephedrine. More Patients in group DS required intraoperative sedation and requested early request for analgesia as compared to patients in group CS and the difference was statistically significant (P<0.05). Ephedrine was required in 27 (50%) patients in Group CS whereas no patient required intraoperative ephedrine in DS group (P < 0.001). patient as well surgeon satisfaction was statistically significantly higher in DS group (P < 0.001) (Figure 2).

Highest level of sensory blockade, motor block, Time to maximum sensory block level, voiding time and time to discharge were compared in both the groups. Highest level of sensory level was T7 and T8 in CS and Group DS respectively. Time to maximum sensory block level was found to be comparable in both the groups whereas voiding time and time to discharge was higher in Group CS and the difference was statistically highly significant (P < 0.001) (Table 2).

Finally, the analysis of adverse events in both the groups showed that incidence of hypotension bradycardia, nausea and shivering was significantly higher in Group CS as compared to Group DS and the difference was statistically significant (P < 0.05). The redo rate in Group CS and DS was found to be 11 (20.37%) and 2(3.7%) respectively and the difference was statistically significant (P < 0.006) (Table 3).

4. DISCUSSION

In the last decade, the trend of ambulatory liposuction procedures increased. Earlier these procedures were being done mostly under general anesthesia. However, the morbidity and mortality associated with general anesthesia mandated anesthetists to search for the alternative ways for providing safer anesthesia in these patients. Nowadays these procedures are mostly done under spinal anesthesia[9].

Lidocaine, mepivacaine and prilocaine were commonly used for spinal anesthesia however

Table 3: Comparison of adverse effects in studied cases.

Variable	Group CS (N = 54)	Group DS (N = 54)	Chi-square	P-value
Hypotension	8 (15.4)	0 (0.0)	8.986	0.002*
Hypertension	0 (0.0)	2 (3.7)	1.963	0.257
Tachycardia	0 (0.0)	2 (3.7)	1.963	0.257
Bradycardia	8 (15.4)	0 (0.0)	8.986	0.002*
Nausea	12 (23.1)	2 (3.7)	8.673	0.003*
Vomiting	4 (7.7)	0 (0.0)	4.317	0.054
Shivering	16 (30.8)	4 (7.6)	9.445	0.002*
Headache	2 (3.8)	0 (0.0)	2.117	0.238
Redo operation	11 (20.37)	2 (3.7	7.497	0.006*

increased incidence of transient neurologic symptoms (TNS) has led anesthetists to shift to bupivacaine which is reported to have lowest incidence of TNS (0–1.3%) making it an attractive alternative.[10] However since it's a long acting local anesthetic it was found to be associated with increased duration of hospital stay. Use of diluted and low dose bupivacaine is associated with decreased incidence of TNS without significantly increased duration of hospital stay.[11]

The novelty of this study finding was that low dose, diluted spinal anesthesia was enough as a sole anesthesia, in tumescent liposuction procedures done for lower limb, with the help of tumescent local anesthesia solution. Moreover, patient satisfaction increased, as in group DS patients experience less dense block and less numbness. Considerable decreased rate of liposuction reoperations was reported, which could be explained by the ability to intraoperatively assess suctioned areas by asking patient to stand up with support and correct any required changes in Group DS. Our results confirmed that the use of low dose, diluted bupivacaine not only provides a satisfactory anesthesia with early ambulation in liposuction procedures, but also help in decreasing reoperation rates.

The level of the sensory block was comparable between both groups without statistical difference. The sensory block level has been reported to be affected by many factors, including patient positioning and the volume, density, concentration and temperature of the injected local anesthetic.[12] In our study, volume, temperature and patients' position were the same, concentration and density was different. Density is the main determinant of the level of the block, it is possible that dilution of the local anesthetic with normal saline rendered the DS solution more isobaric, with relatively small difference in the sensory block levels in both groups. The sensory block duration in the Group CS was significantly longer than in the Group DS. Similar findings were also reported by the authors such as Gordley Pet al. [13]

The first request for analgesia was significantly prolonged in the Group CS, which was consistent with a study by Kooger I et al.[14] in which authors reported that use of heavy bupivacaine led to a delay in the first request for analgesia. The use of diluted bupivacaine resulted in shorter hospital stay. Similar findings were also reported by the authors such as Sarkar P et al.[15] and Collins TC et al.[16]

Martyr and Clark have studied the effects of two different doses of intrathecal bupivacaine (7.5 and 12 mg) on patients undergoing repairs of fractured femur necks, finding no significant statistical differences in the hemodynamic responses of both groups. [17] In contrast, Ben-David et al. found that use of low dose bupivacaine (4 mg) resulted in more hemodynamic stability than use of a higher bupivacaine concentration (10 mg). Findings of our study was similar to study conducted by Ben-David et al. [18]

The Group DS showed a substantial reduction in the time to void, which was also consistent with the results of several previous studies in which it was reported that the time to voiding differed substantially from 170 to 240 min based on bupivacaine concentration, with a more prolonged time related to a higher concentration.

In the present study, there were no major complications recorded in either group, and the incidence of adverse effects was limited, a finding that has also been reported by many other studies.[19,20]

5. LIMITATIONS

Small number of cases was the main limitation of this study. Similar study on large number of cases will further substantiate the results.

6. CONCLUSIONS

The use of low dose diluted spinal anesthesia (bupivacaine 7.5 mg) for ambulatory anesthesia during liposuction procedures of the lower limb provides high-quality and satisfactory anesthesia, with less adverse effects and shorter duration of hospital stay.

7.CLINICAL TRIAL REGISTRATION:

The study was registered according to the standards of the Pan African Clinical Trial Registry PACTR 201710002642374.

8.ETHICAL COMMITTEE APPROVAL:

The study was approved by the Ethics Committee of Menoufia University Hospital in Egypt.

9. DATA AVAILABILITY:

The numerical data is available with the corresponding author and can be provided on request.

10. CONFLICT OF INTEREST:

None

11.AUTHORS CONTRIBUTION:

HE- Concept and design of the study; interpreted the results, prepared first draft of manuscript and critical revision of the manuscript

RH- Statistically analyzed and interpreted; reviewed the literature and manuscript preparation; NB- Design of the study, statistically analyzed and interpreted,

preparation of manuscript and revision of the manuscript AE- Concept and coordination of the overall study.

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