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# Pleth Variability Index [PVI] based Intraoperative Fluid Management in Head and Neck Free Flap Reconstructive Surgeries

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# Abstract

**Introduction:** Head and neck reconstructive surgeries involving microvascular free tissue transfer (free flap) poses a major challenge in achieving good cosmetic and functional outcome. Intraoperative fluid administration may be an important determining factor for successful outcome. Static parameters like CVP, MAP, HR for intraoperative fluid administration may not be reliable. PVI is a dynamic noninvasive parameter for intraoperative fluid administration and easily obtained by pulse co-oximeter derived value. PVI enables goal directed tailor maid fluid administration preventing fluid overload preventing possible tissue oedema, thrombus formation and flap failure.

**Purpose of the Study:** To study PVI based goal directed fluid administration in long duration specialized surgeries and compare the outcome with that of Body mass index (BMI) based fluid therapy.

**Methodology:** A randomized prospective study on eighty patients of head and neck surgery involving free flap of four to five hour duration was conducted, one group of forty patients receive fluid therapy based on body weight i.e. 6 - 8 ml intravenous fluid/kg of body weight i.e. 6-8ml intravenous fluid/kg of body weight. Another (study) group of forty patients received intraoperative fluid therapy based on pulse oximetry derived PVI value (range 4 - 11).

**Data Collected:** MAP, total crystalloid and colloids transfused, urine output, thromboelastography parameters [R, K, ALPHA, MA and LY30], Blood lactate levels in both groups. Categorical data on each parameter obtained through classification analysed using cross tabulation procedure and Chi-square test of independence to study association of study groups and variables. The scale variables were compared between two groups using independent sample 't' test. Fort test of significance cut off 'p' value was taken as 0.05.

**Findings:** The PVI group data results showed significantly less total fluid administration, normal Blood lactate levels and Thromboelastography parameters within normal range compared to patients in group receiving intraoperative fluid based on body weight, which was statistically significant.

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**Significance:** Adequate tissue perfusion and prevention of hypocoagulability and hypercoagulability in the study [PVI]group may help in better microvascular free flap outcome.

**Conclusion:** Pleth variability Index may be a good alternative for goal directed intraoperative fluid management avoiding fluid overload, is non-invasive requiring minimum space in operating room. We also recommend routine Thromboelastography in this group of patients at the end of surgical procedure as a guide to assess coagulation status.

Keywords: Pleth Variability Index; Fluid; Free Flap Surgery

### Abbreviations

FF: Free Flap; GDFT: Goal Directed Fluid Therapy; SVV: Stroke Volume Variation; PVI: Pleth Variability Index; PI: Perfusion Index

### Introduction

Reconstructive free flap (FF) surgery in head and neck is a complex method of wound closure post resection of malignant lesions. Free flaps have their circulation detached and re-anastomosed distantly (micro-anastomosis). Free flaps are particularly vulnerable to ischemia. Primary ischemia is the time from clamping of the vessels to anastomosis while secondary ischemia is time between subsequent hypo-perfusion till vascular anastomosis. Survival of FF depends on adequate blood flow. Hypo-perfusion is detrimental, preventable with anesthetic technique and appropriate fluid therapy. Intra-operative fluid therapy is challenging and is important determining factor for a successful outcome. There is limited evidence regarding standard fluid therapy in flap reconstructive surgery. Use of goal directed fluid therapy (GDFT) keeping stroke volume variation (SVV) < 13% has been advocated in various studies [1].

Pleth variability index [PVI] is a dynamic parameter, non-invasive, for intra-operative goal directed fluid administration in mechanically ventilated patients via pulse co-oximeter waveform analysis.

PVI is calculated by measuring changes in perfusion index (PI) over a time interval where one or more complete respiratory cycles have occurred displayed as percentage (0 - 100%).

Co-oximeter is portable, can be used by all OT personnel, is reliable and occupies minimum space. Thromboelastography (TEG) was developed first by Hartert in 1948 and reviewed largely as a research tool. However in 1990s resurgence of interest in technique that evaluate the viscoelastic properties of whole blood during the perioperative period. TEG is point of care technique for rapid assessment of perioperative coagulability changes, helps to detect hypercoagulable (prothrombotic) or hypocoagulable state.

### Aim of the Study

To compare PVI guided intra-operative fluid administration with that of standard care fluid administration in patients undergoing head and neck onco-surgery (excision of malignant lesion) and micro-vascular FF reconstruction simultaneously, focusing on blood rheology.

# **Objective of the Study**

Primary objective was to compare hemodynamics (heart rate, mean arterial pressure), total intraoperative fluid therapy (crystalloids and colloids), blood lactate level.

Secondary objective was to compare thromboelastography parameters {reaction time(R),coagulation time(K), angle value(alpha),maximum amplitude value(MA) }.

### Methodology

After approval from hospital ethics committee of research protocol, a randomized prospective study was conducted. Informed written consent was obtained. Inclusion criteria was pts. aged 25-65 years,ASA grade 1,2 and 3, undergoing oral oncosurgery -excision with radical neck dissection and free tissue transfer of radial artery free flap or anterolateral thigh free flap and duration of surgery was 6 hours ± 45 minutes. All patients with blood investigations and coagulation profile i.e. BT,CT,PT,aPTTk,INR within

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normal limits were included for the study.

Duration of surgery exceeding 7 hours, patients on antiplatelet medications, anemia (Hb<8g %), patients with dysrhythmias, patients showing abnormal baseline ABG (blood lactate) and TEG parameters were excluded from the study.

Patients were randomized into groups by using the numbers generated by computer(80 subjects assigned to 2 groups 40 to each group control and PVI) by online randomization tool http://www. graphpad.com/qickcalc/index.cfm on the morning of surgery.

Study was Registered at clinicaltrials.gov Identifier; NCT03116178.

Total 80 patients were included in the study.

40 patients were included in control group. In them, intraoperative standard care fluid therapy based on body weight was given. Blood loss upto 10% of estimated blood volume was replaced with colloid/crystalloid at the discretion of attending anesthesiologist. Urine output > 0.5 ml/kg/hr was maintained. Rest of the management was as per departmental protocol.

In the PVI (Plethysmography variability index) group, 40 patients received PVI (Masimo U.S.A. RAD-7 pulse co-oximeter) guided fluid therapy, maintaining PVI value < 13%. Maintenance fluid at 1.5 - 2 ml/kg/hr was given keeping PVI between 9 - 11%. If PVI>13% persisted for > 5 minutes, boluses of 200 ml crystalloid was given till return of PVI to < 13%. Blood loss upto 10% estimated blood volume was replaced by colloids. Noradrenaline (0.01 mcg/kg/min) titrated if MAP < 60 mm Hg (Mean arterial pressure) after bolus fluid therapy as per PVI.

Common to both groups were crystalloids (plasmalyte), colloid (volulyte), blood loss: more than maximum allowable blood (MABL) was replaced with blood. ABG (Arterial blood gas) analysis and TEG (Thromboelatography) analysis was done at the end of surgery. Capillary sugar and free flap blood sugar was done after wound closure.

Standard monitoring was done including urine output and pulse-oximeter based pleth variability index (Masimo Corp. Irwin USA) co-oximeter recordings in study group. Propofol was used as induction agent, combination of fentanyl and morphine for analgesia. Nasal intubation was done with armored tube by video laryngoscopy or awake fibreoptic bronchoscope. Sevoflurane in oxygen and nitrous oxide was used for maintenance of anesthesia. Atracurium was used as muscle relaxant. Controlled ventilation was done to keep normocapnia. Retention of nasal ETT (endotracheal tube) kept overnight and guarded extubation was done in PACU.

#### The following data were recorded:

- **Preoperative:** Demography, ASA grade.
- Intraoperative: Body temperature, mean arterial pressure (MAP), total fluid administered, blood loss, blood transfused, urine output, blood lactate levels at the end of surgery, TEG parameters (R, K, Alpha, MA [ TEG trace]) at the end of surgery, random blood sugar, free flap sugar (post anastomosis) by needle prick.

### Sample size calculation

The study was about comparing parameters between two independent groups with the help of independent sample 't' test to determine if two population means m1, m2 are equal. Therefore, minimum sample size required for independent sample 't' test has been computed by using G\*Power 3.1.9.2 software under the guidance of a Bio-statistician [2-4].

### **Statistical analysis**

Categorical data on each of the parameter obtained through

Input	Output
Tail(s) = Two	Noncentrality parameter $\delta = 2.8703223$
Effect size d = 0.65	Df = 76
α error prob = 0.05	Sample size group 1 = 39
Power (1-β error prob) = 0.80	Sample size group 2 = 39
Allocation ratio N2/N1 = 1	Total minimum sample size = 78
Critical t = 1.9916726	
However, we have studied 80 samples, 40 in each group [4].	

### Table

classification were analyzed using cross tabulation procedure and Chi-square test of independence to study the association of study groups and variables. The scale variables were compared between

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two groups using independent sample 't' test. Comparison of mean  $\pm$  SD between scale variables have been done using independent sample 't' test. For test of significance cut off 'p' value was taken as 0.05.

# **Results**

The mean age of Group PVI was  $50.48 \pm 11.7$  years and mean age of Group Control was  $43.98 \pm 12.12$  years (Figure 1). The mean weight of Group PVI was  $69.68 \pm 13.72$  kg and mean weight of Group Control was  $67.80 \pm 10.36$  kg and there was no significant difference in weight of the two groups (p = 0.491). The distribution of gender in control and study group were not significantly different (p = 0.456) (Figure 2). Distribution of ASA physical status and the type of surgery is also shown in figure 3-8 respectively.

The mean crystalloids infused in group control (2.51  $\pm$  0.58l)



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#### Figure 2: Gender distribution of cases.

Figure 1: Mean comparison of age and weight between two groups.

was significantly higher than that in group PVI ( $2.15 \pm 0.521$ ) with a p=0.005. The mean colloids infused in group control ( $0.65 \pm 0.361$ ) was significantly higher than that in Group PVI ( $0.45 \pm 0.301$ ), (p = 0.008) and the mean total fluid in the control group was significantly higher than the PVI group (Figure 9 and table 1].

Figure 3: ASA grade.

The mean lactate in Group PVI  $(1.35 \pm 0.47)$  was significantly lower than the Control group  $(2.21 \pm 0.94)$  (p = 0.000). The normal lactate level is 1.5 - 2 mmol [5] (Table 1).

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	Groups				
	Control		PVI		
	Mean	SD	Mean	SD	P value
Fluids crystalloids	2 5 1	0.50	2.15	0 5 2	0.005
(lts)	2.51	0.58	2.15	0.52	0.005
Fluids colloids (lts)	0.65	0.36	0.45	0.30	0.008
Total fluids (lts)	3.16	0.75	2.60	0.60	0.000
Comparison of mean of blood lactate levels between two					

groups (N = 40)

		Groups			
	Cont	Control		PVI	
	Mean	SD	Mean	SD	P value
ABG -Lactate	2.21	0.94	1.35	0.47	0.000

**Table 1:** Comparison of total intravenous fluids and lactatebetween two groups (N = 40).

The R time was significantly abnormal in control group as compared to PVI group (p = 0.010). The MA (maximum amplitude) was significantly abnormal in control group as compared to PVI group (p = 0.014) (Table 2).

# Discussion

The two groups were well matched with regard to demography, ASA physical status, type and duration of surgery/anesthesia.



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		Group		
		Control group	PVI group	X <sup>2</sup> , P
TEG_R (in mins.)	Below normal (< 4)	10	2	
	Normal (4 - 8)	22	34	
	Above normal (≥ 8)	8	4	
	Total	40	40	9.238 0.01
TEG_K	Normal (0 - 2)	3	1	
	Normal (2 - 4)	33	37	
	Above normal ( $\geq$ 4)	4	2	
	Total	40	40	0.721 0.396
TEG_ALFA	Below normal (< 47)	4	3	
	Normal (47 - 74)	33	36	
	Above normal (> 74)	3	1	
	Total	40	40	1.273 0.529
TEG_MA	Below normal (< 54)	2	3	
	Normal (54 - 72)	28	36	
	Above normal (> 72)	10	1	
	Total	40	40	8.564 0.014

 
 Table 2: Association of TEG parameters between control group and PVI group.

Figure 10: TEG machine.

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In the present study PVI (Plethysmography variability index) guided GDFT (Goal directed fluid therapy) resulted in fluid optimization, volume of fluid transfusion in control group was higher and difference was statistically significant [6].

In a metaanalysis study by Chu., *et al*. they concluded that pleth variability index has a reasonable ability to predict fluid responsiveness [7].

Fu., *et al.* in their prospective study concluded that SVV (Stroke volume variation) and PVI could be used to predict fluid responsiveness [8].

Cannesson., *et al.* reported PVI value > 14% predicted fluid responsiveness, reducing PVI below 13% by volume loading-maximizes stroke volume intraoperatively.

Present study regarded PVI > 13% (Plethysmography variability index) as the threshold for fluid bolus, maintaining it between 11 to 13%. We found that blood lactate levels in PVI group was within normal limits and lower as compared to control group. This finding was in synchrony with findings of Forget., *et al*, Jan Benes., *et al*. and Ivan., *et al* [5,6,9].

A lower blood lactate level indicates overall better perfusion and oxygen delivery to free flap as blood lactate levels is used as a marker in assessing occult hypo perfusion. They are early indicators of unfavorable outcome.

Free flap reconstruction is the gold standard for oral cancer surgery, as it provides best aesthetics, and good functional results. FF (free flap) Success rates world over are 95% [10].

FF loss occurs at the rate of 1 - 6% average 4.4% [11]. Risk factors of total flap loss may be unclear. Clinical and experimental data indicate flow behavior of blood (rheology) which is a major determinant of tissue perfusion may be a major factor. Hypercoagulable state leads to postoperative thrombosis in microvascular FF, excessive peri-op fluid administration-flap loss [1].

The main cause of free flap failure was tissue oedema which reduces the flow to the flap. It may be due to trauma from handling, excessive hemodilution, excessive crystalloids, failure of lymphatic drainage, prolonged ischemia time.

Our study revealed TEG (Thromboelastography) primary parameters were hypercoagulable or hypocoagulable in control group as against PVI group where significant number of patients had TEG parameters (R, K, and alpha and MA values) within normal range. Hemodilution due to crystalloids induces a hypercoagulable state TEG parameters) [12-15]. Another study by Topcu., *et al.* in major orthopedic surgeries, effect of crystalloid/colloid on primary TEG parameters analyzed and the results were similar to our findings [16]. Monkhouse [17] reported moderate hemodilution with crystalloids, enhanced coagulability which was later confirmed by Janvrin SB., *et al.* [18]. Venous thrombus in free flaps is the result of thrombosis in postoperative period and is around 10 - 20% is most common cause of flap loss [10].

Excessive IV (intravenous) crystalloids causes hemodilution possibly by enhancement thrombin formation due to decrease in antithrombin-III, causes a procoagulant effect leading to venous thrombosis [14].

Avoidance of excessive crystalloid use-associated with improved flap outcome [19].

Also, IV colloids have an antiplatelet action resulting in hypocoagulability [20].

Thus. the anesthetic goals of FF surgery remains good tissue perfusion (adequate Mean arterial pressure and normal lactate levels), fluid optimization, and achieving normal blood coagulability which can be achieved via Goal directed fluid therapy.

#### **Study Limitations**

Potential weaknesses in the design of our study include:Study was not blinded.

- 1. Study was not blinded.
- Study was limited to only two categories of reconstructive surgery.
- 3. Skilled technical person is required for TEG assessment and has to be performed within 3-4 minutes of phlebotomy.
- 4. Skilled technical person is required for TEG assessment and has to be performed within 3-4 minutes of phlebotomy.

### Conclusion

Pulse oximetry based, PVI guided intraoperative fluid administration in long duration free flap reconstruction surgery helped to achieve optimum fluid therapy maintaining stable hemodynamics, low serum lactate levels indicating good tissue perfusion and nor-

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mal blood coagulability -conditions favorable for FF survival.

Thromboelastography system a point of care testing may be utilized by the anesthesiologist for rapid assessment of any hypocoagulable or hypercoagulable states in this clinical setting, so that necessary step can be taken to prevent free flap loss or failure.

# **Conflict of Interest**

No financial relationship with any organization and no conflict of interest.

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