

# To compare intraoperative goal directed fluid therapy by trans-oesophageal Doppler vis-à-vis FloTrac™ in patients undergoing living related renal transplantation-a prospective randomised controlled study

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## ABSTRACT

**Background:** Optimal intra-operative fluid therapy in renal transplantation (RT) is essential to ensure adequate graft function while preventing fluid overload related complications. This RCT was to compare the intraoperative goal directed fluid therapy (GDFT) based either on corrected flow time (CFT), measured by trans oesophageal Doppler (TED) or on the stroke volume variation (SVV), by FloTrac in patients undergoing living donor RT. **Methods:** This prospective, randomised controlled trial (RCT) was done on 60 end stage renal disease (ESRD) patients, American Society of Anaesthesiologists(ASA) grade III–IV, age 18 to 65 years of either sex, scheduled for living donor RT under general anaesthesia. They were randomly divided into two groups: TED group ( $n = 30$ ) and FloTrac™ group ( $n = 30$ ) and administered GDFT, based upon CFT (TED) and SVV (FloTrac™). The primary outcome was to compare the total fluid and number of fluid boluses administered intraoperatively, while the secondary outcomes were to compare any postoperative complications due to fluid overload and allograft function, assessed by serial serum creatinine levels up to 90 days postoperatively. **Results:** The mean total intra-operative fluid [ $3991.67 \pm 856.32$  vs.  $3543.33 \pm 1131.35$ ,  $P = 0.089$ ] and the amount of fluid administered per kg body weight per hour [ $13.32 \pm 4.67$  vs.  $11.82 \pm 4.76$ ,  $P = 0.222$ ] were lesser in the FloTrac compared to TED group, though not statistically significant. However, the postoperative incidence of allograft dysfunction, including rejection ( $P = 0.743$ ) and acute tubular necrosis (ATN) ( $P = 0.999$ ), and other complications ( $P = 0.643$ ) were comparable. **Conclusions:** Both TED and FloTrac devices can be used effectively to guide GDFT in RT, However, lesser total fluid was required in the FloTrac group, which may lead to a lesser number of fluid-related postoperative complications.

**Key words:** Corrected flow time, FloTrac™, goal directed fluid therapy, living donor renal transplantation, stroke volume variation, transoesophageal Doppler

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## INTRODUCTION

End-stage renal disease (ESRD) patients have a varying severity of systemic disorders especially cardiovascular and pulmonary, apart from dialysis dependency, immunosuppression and polypharmacy, which leads to high morbidity and mortality.<sup>[1,2]</sup> Renal transplant (RT) improves the quality of life in ESRD. To ensure graft function after RT, it is essential to maintain optimal intravascular volume and adequate renal

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blood flow. Reduced renal perfusion, as caused by low mean arterial pressure (MAP) and aggravated by the impaired auto-regulation of the denervated kidney, can result in ischemia and poor graft function.<sup>[3]</sup> However, overzealous fluid administration may precipitate congestive heart failure and pulmonary oedema. There is narrow margin between too little intraoperative fluid causing impaired renal perfusion or too much leading to damage of endothelial glycocalyx<sup>[4]</sup> and thereby overload and postoperative complications.<sup>[5,6]</sup> Earlier, it was the routine practice to titrate fluid to maintain central venous pressure (CVP) of 8–12 mmHg and MAP >80 mmHg during RT.<sup>[7]</sup>

The FloTrac™ (Vigileo™ system) through arterial based cardiac output measures stroke volume variation (SVV) and trans-oesophageal Doppler (TED) by measuring the velocity of descending aorta using the Doppler principle measures corrected flow time (CFT) (reflects the left ventricle filling pressure), both used as a marker of fluid responsiveness.<sup>[8]</sup> As per our literature search, no RCT so far has compared TED with FloTrac in patients undergoing RT. The primary outcome of our study was to compare TED with FloTrac for intraoperative goal-directed fluid therapy (GDFT) during living donor related RT. The secondary outcome was to assess the impact of GDFT on the graft outcome and postoperative fluid-related complications.

## METHODS

This prospective, randomised controlled trial was conducted after approval by the Institutional Ethics Committee (IEC: 2017-67-MD-97), and registry with the Clinical Trials Registry of India (CTRI/2017/07/009159) from August 2017 to March 2019. All patients gave written informed consent, as per the declaration of Helsinki and good clinical practice guidelines. The 60 ESRD patients of American Society of Anaesthesiologists (ASA) grade III/ IV, aged 18 to 65 years of either sex, scheduled for living donor RT under general anaesthesia (GA) were randomised and divided into two groups to receive GDFT guided either by the TED (based upon CFT) or FloTrac™ (based upon SVV).

The patients who did not consent or in whom the insertion of either of the two proposed devices by their manufacturers was contra-indicated or posed a risk {such as atrial fibrillation or other severe arrhythmias, aortic coarctation, significant valvular heart disease, prior upper airway or oesophageal surgery or disease (including cancer, stricture,

varices or diverticulum)}, and undergoing second transplantation and re-exploration were excluded.

The patients were randomised into two groups of thirty each: the TED group ( $n = 30$ ) and FloTrac™ group ( $n = 30$ ), using block randomisation method by taking block size of 10. Blocks were performed by the anaesthesiologist not involved in the study. Patients and attending nurse were kept blinded to the block. The case was performed by the same team of anaesthesiologists who handed over the final results to the investigator in a sealed envelope.

All the patients were subjected to detailed pre-anaesthetic evaluation and optimisation. All the surgeries were performed under balanced GA with endotracheal intubation and epidural analgesia (placed before induction after local anaesthetic xylocard 2% infiltration and loading with 0.25% bupivacaine 6-8 ml given before start of surgery). Routine monitoring like electrocardiogram, peripheral oxygen saturation (SpO<sub>2</sub>), end tidal carbon dioxide (ETCO<sub>2</sub>), temperature, input-output charting and special monitoring like bispectral index (40-60), invasive arterial pressure and CVP line were used. The patients were induced with intravenous (IV) midazolam [0.05-0.15 mg kg<sup>-1</sup>, fentanyl (1-2 µg kg<sup>-1</sup>), and propofol (1-2.5 mg kg<sup>-1</sup>). The trachea was intubated after rapid sequence induction, with an appropriate-sized polyvinyl chloride (PVC) cuffed endotracheal tube facilitated with rocuronium (0.6 mg kg<sup>-1</sup> IV). Anaesthesia was maintained with desflurane, air, oxygen and intermittent atracurium boluses. Analgesia was obtained with hourly 1 µg kg<sup>-1</sup> fentanyl IV or epidural infusion of 0.125% bupivacaine with fentanyl 1 µg ml<sup>-1</sup>. Ultrasonography (USG) guided central venous pressure (CVP) line was inserted in right internal jugular vein for administering inotropes or vasopressors. CVP was measured but not utilised for guiding fluid therapy.

In both the groups GDFT was used to assess fluid responsiveness and managed accordingly by the same anaesthesiologist group, practising an established institute protocol. All the renal transplantation surgeries were performed by the same surgical team. In the TED group, a 14-F TED probe CardioQP-EDM (Deltex Medical, Chichester, UK) was introduced orally and positioned to obtain CFT, stroke volume (SV), cardiac output (CO) and cardiac index (CI). In FloTrac™ group, the radial artery cannula was connected to a FloTrac™ sensor and Vigileo monitor (Edwards Lifesciences, Irvine, CA, USA) to monitor the SV, SVV, CO, CI,

and systemic vascular resistance (SVR). The patients were given balanced salt solution (BSS) Plasma Lyte A (Baxter India Pvt. Ltd) as per the maintenance fluid requirements of the patient based upon the 4-2-1 rule<sup>[9]</sup> until the completion of renal vascular anastomosis. Following the anastomosis, fluid therapy based on the urine output replacement was performed until the end of surgery. Additionally, when CFT <350 ms in the TED group and SVV  $\geq$  10-12% in FloTrac group, 250 mL of BSS boluses were administered and haemodynamic parameters as above were recorded every 30 minutes intraoperatively. Otherwise, fluid therapy was continued on maintenance basis in both the groups.

All the living kidney donors underwent nephrectomy under balanced GA with similar perioperative fluid management protocol. They were administered BSS at the rate of 20-30 mL kg<sup>-1</sup> hr<sup>-1</sup> supplemented by BSS titrated to match the urine output from the start of surgery until the renal vessels were clamped.

The total fluid was calculated as the fluid, blood products given before reperfusion, divided by the patient's body weight and duration from initiation of anaesthesia until allograft reperfusion (in hours). Methylprednisolone (500 mg IV) was given in all recipients before opening of clamps. MAP was kept >90 mmHg at the time of graft reperfusion and thereafter. Hypotension, considered if MAP <65 mmHg, in presence of an adequate CFT and SVV with lower SVR, was managed by IV phenylephrine intraoperatively in both the groups. Postoperatively, MAP >100 mm Hg was maintained by the use of vasopressors (norepinephrine infusion) after ensuring positive fluid balance.<sup>[6]</sup> At the end of the surgery muscle relaxation was reversed with neostigmine 0.05 mg kg<sup>-1</sup> IV and glycopyrrolate 0.01 mg kg<sup>-1</sup> IV. All the patients were extubated and then transferred to the kidney transplant intensive care unit (KICU).

In the KICU, the patients were monitored and evaluated daily for haemodynamics, input and output charting, serial haematological, biochemical, nephrological biomarkers, immunosuppression levels and sonographic assessment of the graft and other complications. Postoperatively fluid management was similar in both the groups as per our standard institute protocol, which includes 90–100% replacement of hourly urine output in the first 48 hours followed by 80% replacement of daily urine output until the patient was discharged. The immunosuppressant medications were given as per standard protocol.

Graft function was assessed by measuring serial serum creatinine levels on postoperative days 0, 1<sup>st</sup>, 2<sup>nd</sup>, 7<sup>th</sup>, 10<sup>th</sup>, 30, 60<sup>th</sup>, and 90<sup>th</sup>. Immediate graft function was defined as fall in serum creatinine to below pre-transplant levels within first 48 hours postoperatively. Graft dysfunction was suspected whenever there was failure of serum creatinine to decline, rise in serum creatinine, the requirement of dialysis postoperatively, or decrease in urine output.<sup>[10]</sup> Histopathological examination of these cases by renal allograft biopsy in terms of no rejection, acute rejection, the possibility of rejection and acute tubular necrosis (ATN), as per Banff criteria.<sup>[11]</sup> Postoperative complications pertaining to fluid therapy as oxygen desaturation, the requirement of ventilation and visible tissue oedema were observed.

There is no such previous study with similar objectives, on the basis of which we could decide the sample size. Hence for this study we had to estimate the sample size based on assumptions of the effect size (supposed to be detected between two group or within the group). We had to give intraoperative GDFt, based on boluses, as decided by either of two techniques, several times repeated during the study duration to calculate the total fluid or number of boluses given) effect size of 0.15 (for mean difference), at minimum two-sided 95% confidence interval and 80% power of the study. Sample size for the TED and FloTrac group came out to be 28 in each (in a within-between interaction of Repeated measures analysis of variance (ANOVA) study designs, with two study groups and each group had at least 5 repeated observations). Sample size was estimated using software G Power version - 3.1.9.2 (Düsseldorf university, Germany). To rule out any dropouts, 30 patients were taken in each group finally.

The normality of the continuous data was assessed and a variable was considered normal when standard deviation (SD) was <½ mean value. Normally distributed data were presented in mean  $\pm$  standard deviation, otherwise median (interquartile range) was used. Categorical data were presented in frequency (%). To compare the means between the two independent groups (two fluid management methods, i.e., TED and FloTrac™), independent samples t-test, while for proportions, Chi-square test and z test were used. To test the change in means over the different time points, the Repeated Measures ANOVA (RMA) test was used. In case the RMA test was found significant, pair-wise multiple comparisons were performed to find out the exact pairs

between which mean differences were significant. Error bar graph (showing mean ± 1 SD) was used to present the trend of the means over time. A *P* value <0.05 was considered as statistically significant. Statistical Package for Social Sciences, version -23 (SPSS-23, IBM, Chicago, USA) was used for analysing the data.

**RESULTS**

Allocation of patients is shown in CONSORT diagram Figure 1. The demographic profiles, mean baseline heart rate (HR), MAP, CVP, and serum creatinine were comparable in both the groups [Table 1]. Baseline CO between the groups differed significantly (*P* < 0.001), but subsequent values were not significant. The difference in CO, may have been because of the two different

technologies and working principles of machines. Intra-operatively haemodynamic parameters were recorded every 30 minutes from induction until the end of the surgery. The total duration of surgery ranged from 240 to 300 min, but parameters were compared till 240 min or the end of the surgery, whichever was earlier. The mean HR, MAP, CVP were comparable between both the groups (*P* > 0.05) [Table 2]. A weak correlation (Pearson correlation coefficient >0.05) was observed between the CFT (TED group) and SVV (FloTrac group) with CVP measured.

There was no statistically significant difference in the total intra-operative fluid [3991.67 ± 856.32 vs. 3543.33 ± 1131.35 ml, *P* = 0.089] and the amount of fluid administered per kg body weight per hour

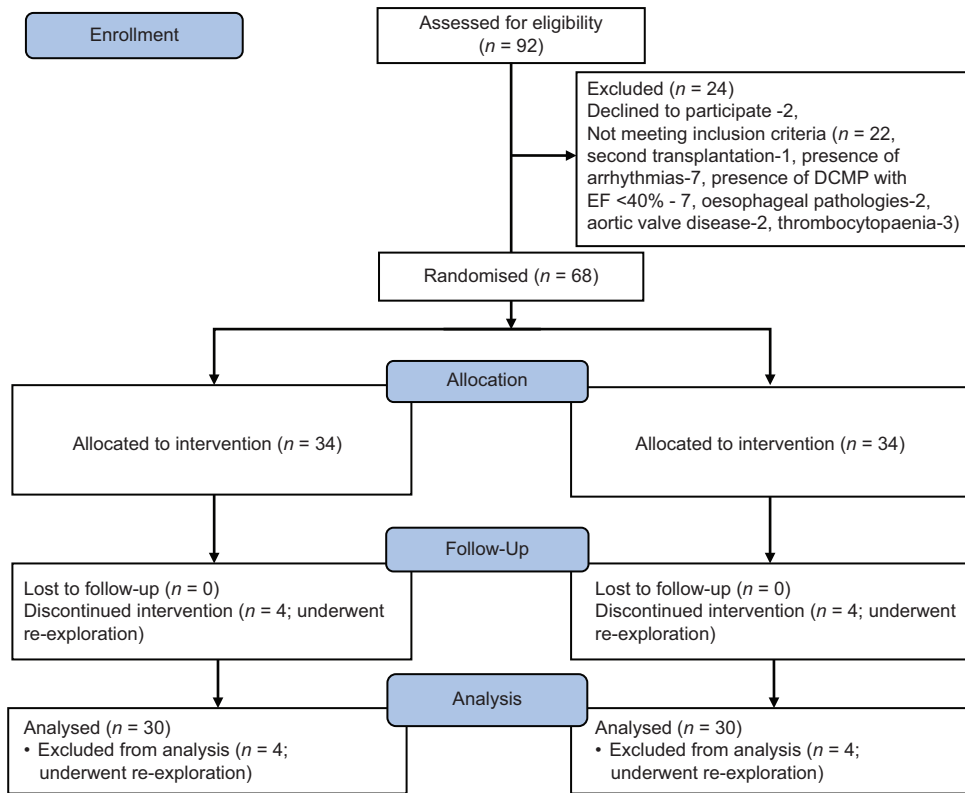


Figure 1: CONSORT flow diagram

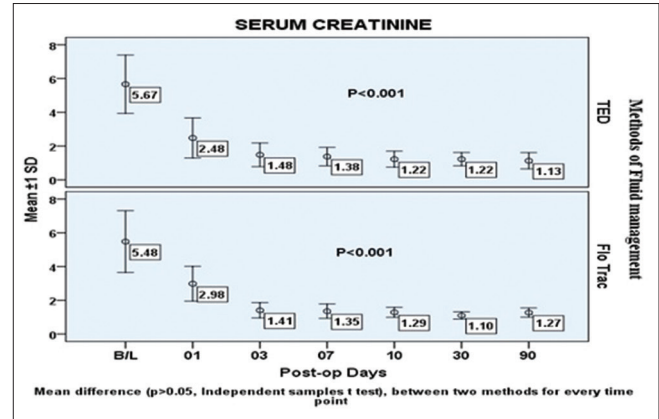
Table 1: Comparison of demographic and baseline clinical parameters between the groups				
Variables (Mean±SD)	TED (n=30)	FloTrac (n=30)	Total (n=60)	P
Age (years)	31.33±8.25	35.23±11.32	33.28±10.02	0.133
Weight (kg)	58.17±12.77	58.10±10.61	58.13±11.65	0.983
Sex (Male) <sup>#</sup>	26 (86.7%)	29 (96.7%)	55 (91.7%)	0.161
HR (baseline) per min	86.23±16.29	90.47±18.03	88.35±17.17	0.344
MAP baseline) (mmHg)	105.33±19.29	100.90±15.91	103.12±17.67	0.336
CVP (Baseline) (mmHg)	9.37±3.01	8.64±3.09	9.02±3.05	0.371
CO (L/min) (baseline)	4.0±1.37	6.9±1.97	5.5±2.23	<0.001
S. Creatinine (mg/dl) (baseline)	5.75±1.65	5.49±1.87	5.62±1.75	0.563

<sup>#</sup>Chi-square test used, Independent samples *t*-test used, *P*<0.05 significant. HR – Heart rate; MAP – Mean arterial pressure; CVP – Central venous pressure; CO – Cardiac output

[13.32 ± 4.67 vs. 11.82 ± 4.76, *P* = 0.222] between both the groups. The FloTrac™ group, however, required significantly lesser number of fluid boluses [4.50 (2-7.25) vs. 1 (0-2.25), *P* < 0.001] [Table 3].

The mean serum creatinine on 0, 1<sup>st</sup>, 2<sup>nd</sup>, 7<sup>th</sup>, 10<sup>th</sup>, 30<sup>th</sup>, 60<sup>th</sup> and 90<sup>th</sup> postoperative days was comparable in both the groups [Figure 2]. Post-transplant, 16 patients (53.3%) in the TED group and 18 patients (60.0%) in FloTrac™ group were suspected to have graft dysfunction; for that they underwent renal allograft biopsy as per institutional protocol. Three patients (10%) in each group were found to have acute tubular necrosis (ATN) on histopathological examination. The percentage of histopathological evidence of renal allograft rejection was similar in both the groups [5 (16.7%) versus 6 (20%); *P* = 0.743]. In the rest of the patients with

suspected graft dysfunction, allograft biopsy showed no evidence either of rejection or ATN [Table 3].



**Figure 2:** Comparison of trend of post-operative serum creatinine between the two groups

**Table 2: Variation of intra-operative haemodynamic variables over time between both the groups**

Time	Baseline	30 min	60 min	120 min	180 min	240 min	<i>P</i>
Heart rate per min							
TED	86.2±16.3	84.5±18.1	83.5±18.3	83.0±19.2	84.3±19.8	87.1±22.4	0.120
FloTrac	90.5±18.1	82.9±16.5	84.1±16.1	86.0±14.2	85.3±15.3	88.4±15.3	0.014
<i>P</i>	0.344	0.733	0.840	0.49	0.833	0.799	
Mean Arterial Pressure (MAP) mmHg							
TED	105.3±19.3	100.5±18.1	103.3±17.2	100.1±17.4	102.8±18.4	105.2±19.8	0.240
FloTrac	100.9±15.9	96.5±18.9	98.1±20.9	98.0±20.9	99.9±17.3	102.7±19.0	0.235
<i>P</i>	0.336	0.409	0.301	0.679	0.522	0.615	
*Central Venous Pressure (CVP) mmHg							
TED	9.4±3.1	9.5±2.9	10.0±3.4	10.0±2.5	10.2±2.8	11.1±3.2	0.076
FloTrac	8.4±3.2	9.1±3.5	8.9±3.3	9.7±3.6	9.9±3.3	10.5±3.8	0.008
<i>P</i>	0.235	0.637	0.234	0.652	0.736	0.558	
Cardiac Output (CO) L/min							
TED	4.0±1.4	3.94±1.4	3.9±1.5	3.9±1.3	3.9±1.3	4.0±1.4	0.753
FloTrac	6.9±1.9	7.32±1.9	7.4±2.2	7.7±2.1	7.5±2.1	6.9±1.9	0.139
<i>P</i>	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Corrected flow time (FTc) millisecond							
TED	351.1±66.1	350.4±63.8	348.8±50.9	352.9±51.4	352.6±60.9	364.9±42.6	0.455
* <i>r</i> ( <i>P</i> )	0.275 ( <i>P</i> =0.142)	-0.039 ( <i>P</i> =0.839)	-0.182 ( <i>P</i> =0.337)	-0.267 ( <i>P</i> =0.154)	-0.074 ( <i>P</i> =0.705)	0.077 ( <i>P</i> =0.794)	
Stroke Volume Variation (SVV)							
FloTrac	7.1±2.9	7.2±3.2	7.63±2.9	7.5±3.9	8.4±3.4	7.1±3.4	0.255
* <i>r</i> ( <i>P</i> )	-0.138 ( <i>P</i> =0.484)	-0.251 ( <i>P</i> =0.190)	-0.385 ( <i>P</i> =0.039)	-0.307 ( <i>P</i> =0.106)	0.024 ( <i>P</i> =0.913)	-	

§Repeated Measures ANOVA used, #Independent samples *t*-test used. \*Pearson correlation coefficient was calculated with CVP/TED/FloTrac, *P*<0.05 significant

**Table 3: Comparison of intra-operative fluid requirement and renal allograft outcome**

Variable	TED (n=30)	FloTrac™ (n=30)	Total (n=60)	<i>P</i>
§Total Fluid (ml) (Mean±SD)	3991.67±856.32	3543.33±1131.35	3767.50±1020.13	0.089
§Fluid per kg body weight per hour	13.32±4.67	11.82±4.76	12.57±4.74	0.222
*No. of Boluses	4.50 [4.77±3.38]	1 [1.73±2.15]	2 [3.25±3.20]	<0.001
#Graft rejection	5 (16.7%)	6 (20%)	11 (18.3%)	0.743
#ATN	3 (10%)	3 (10%)	6 (10%)	0.999
#Post-operative complications	3 (10%)	2 (6.6%)	5 (8.33%)	0.643

Data presented in Mean±Standard deviation/Median (Inter-quartile range)/Frequency (%). §Independent samples *t*-test, \*Mann Whitney U test used. #Chi-square test/Z test for two proportions used. *P*<0.05 significant



Three patients (10%) in the TED group and two patients (6.6%) in FloTrac™ group developed post-operative complications pertaining to fluid therapy. Out of these five patients, three were having visual tissue oedema (2 in TED and 1 in FloTrac™ group) in the immediate post-operative period. The difference in postoperative complications of fluid therapy between the two groups was not statistically significant ( $P = 0.643$ ) [Table 3].

## DISCUSSION

The primary outcome of our study was to compare TED with FloTrac for intraoperative goal-directed fluid therapy (GDFT) during living donor related RT.

On comparing both the devices we found no significant difference between the total amount of fluid administered (in ml and in ml kg<sup>-1</sup> h<sup>-1</sup>) between the two groups. However, the lesser requirement of intra-operative fluid in the FloTrac group as compared to TED group may be significant in RT recipients. Regarding the fluid therapy related post-operative complications, we found comparable such incidence between TED and FloTrac group. It may be deduced that both TED and FloTrac™ guided fluid therapy can be used in place of CVP with lesser risk of complications of fluid overload.

Standard pressure-based and static indices like CVP, pulmonary capillary wedge pressure, and MAP fail to show the actual real-time volume status in high-risk surgical patients.<sup>[12,13]</sup> This invented newer dynamic indices based GDFT to accurately assess fluid responsiveness.<sup>[14,15]</sup> These newer techniques along with adequate haemodynamic optimisation in various high-risk surgeries including transplantation had improved the early recovery and significantly reduced the postoperative complications.<sup>[16,17]</sup> In renal transplant recipients, even CFT (TED) guided fluid therapy had proven better outcomes to CVP with lesser side effects. Recent studies have proven that both TED or FloTrac can be used as individualised GDFT in renal transplantation safely but no RCT has compared both the techniques as was done in this study.<sup>[18,19]</sup>

Similar results were also found, as significantly lower requirement of fluid and fewer complications in the FloTrac group<sup>[17,18]</sup> or in the TED group<sup>[19-22]</sup> as compared to CVP (conventional) group in RT. Other studies have also proven that dynamic indices of haemodynamic monitoring reduce postoperative complications and hospital stay, short and long-term

morbidity and mortality in various high-risk surgical patients.<sup>[23,24]</sup>

DGF is multifactorial depending on the pathophysiology of the recipient, preoperative optimisation of comorbidities, immunology, immunosuppression and interaction of various treatment modalities.<sup>[25]</sup> Besides these factors, intraoperative fluid management is one of the most important considerations for adequate oxygenation and perfusion. This needs individualised optimal fluid therapy based on the latest haemodynamic monitoring, showing real time intravascular volume and fluid responsiveness.<sup>[26]</sup> The postoperative serum creatinine levels, used to define the allograft function, were comparable in the two groups. However, in the present study, on histopathological examination, incidence of ATN (10%) was considerably lower than in the literature.<sup>[27]</sup> This finding further strengthens the importance of GDFT in RT, as similar results were also found in other recent studies.<sup>[28,29]</sup> In animal renal transplantation, individualised GDFT compared to high-volume therapy did not improve early GFR; however, it reduced tissue inflammation and led to preservation of the glycocalyx.<sup>[30]</sup>

The limitations of this study are that the sample size was small, it was a single centric study, graft function is multifactorial and that was not studied, GDFT, was applied only during the intraoperative phase. Apart from this, the two techniques used in the study have their own limitations. We tried to overcome them by strictly following inclusion and exclusion criteria. Further large scale, multicentric studies are required to prove the superiority of utilisation of SVV as a goal in RT.

## CONCLUSIONS

GDFT guided and based on individualised requirement fluid therapy may have a better option in RT. Both TED and FloTrac devices can be used effectively to guide GDFT in RT, However, lesser total fluid is required in the FloTrac group, which may lead to a lesser number of fluid-related postoperative complications.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and

due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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