Original Article

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Comparison of Restrictive Fluid Therapy versus Conventional Fluid Therapy on Renal Indices in Patients undergoing Major Abdominal and Gynaecological Surgeries: A Tertiary centre experience

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Abstract

Background: Perioperative fluid administration during major abdominal and gynaecological surgeries is done to ensure optimal oxygen supply and tissue perfusion. Restricted fluid therapy produces concentrated urine to reduce availability of water. Osmotic gradient is created and maintained by kidneys which become increasingly concentrated from the cortex to the medulla. Restrictive fluid therapy in abdominal surgery patients is associated with faster return of bowel function, fewer complications and shorter hospital stay. **Subjects and Methods:** The study groups were divided as Conventional ('traditional practice') intravenous fluid group administered balanced salt solution as 10 mL/kg bolus followed by 8 mL/kg/hour as infusion until the end of surgery followed with maintenance infusion at 1.5 mL/kg/hour. The restrictive group fluid regimen administered intravenous fluid bolus limited to 5 mL/kg at induction and Balanced salt crystalloid at 5 mL/kg/hour as infusion was administered until the end of surgery, and bolus colloid/blood was used intraoperatively to replace blood loss (mL for mL); then a postoperative infusion rate of 0.8 mL/kg/hour until cessation of intravenous fluid therapy within 24 hours. **Results:** A significant increase in cystatin levels, a significant decline in serum potassium levels and in GFR (as per CKD-EPI formula based on combination of Cystatin C and Creatinine levels) was observed in both the groups. **Conclusions:** There was no significant difference between two groups for the primary renal function outcomes and electrolyte levels prior to surgery Post-operatively, mean serum urea, creatinine were comparable in both the groups in our study. Serum cystatin c levels were observed to be higher in restrictive group.

Keywords: Restricted fluid therapy, Cystatin C.

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Introduction

Perioperative fluid administration during major abdominal and gynaecological surgeries is done to ensure optimal oxygen supply and tissue perfusion. Tissue oedema and weight gain varying from 3 to 6 kg has been observed due to liberal use of intravenous fluids. [1] Increased incidence of pulmonary morbidity, impaired coagulation, bacterial translocation, sepsis and poor wound healing subsequent to liberal use of intravenous fluid therapy have been observed.[2]

Spinal anaesthesia is a commonly used technique in anaesthetic practice for gynaecological, lower abdominal, pelvic, and lower limb surgeries. Bupivacaine, a long acting amide is appropriate for procedures lasting for 2 to 2.5 hours. Intravenous agents epinephrine, phenylephrine, adenosine, magnesium sulphate, neostigmine and alpha2 agonists like clonidine and dexmedetomidine can be used to prolong duration of surgery.

Intravenous fluid administration helps to replace third-space losses with crystalloids. Liberal volumes of intravenous fluids are administered in perioperative period to reduce preoperative dehydration, circulatory instability associated with general and regional anaesthesia and inadequate tissue oxygen delivery (especially to the bowel), unnecessary blood transfusion and low urine output.[3] It also compensates the preoperative fasting and other fluid deficits, anaesthesia-induced vasodilation, haemorrhage, and accumulation of fluid in extravascular spaces and to enhance tissue oxygen delivery and maintain urine output.[2]

Hemodilution in perioperative period following fluid administration leads to decrease in renal oxygenation thereby leading

to poor renal function.[4] Hypovolemia leads to impairment of circulation thereby reducing oxygen supply to various organs and peripheral tissues leading to organ dysfunction and shock.

Fluid overload causes interstitial edema and local inflammation. It also reduces the capacity to regenerate collagen which leads to slow tissue healing along with increased susceptibility to wound infections, wound rupture, and anastomotic leakage. Fluid overload can also affect the cardiopulmonary function.[5]

Subjects and Methods

The Prospective study was carried out in the department of anaesthesia at a tertiary care hospital in North India and included 60 adult patients (≥18 years) of either sex undergoing elective major Abdominal & Gynaecological surgeries from July 2020 to April 2021 to assess the impact of restricted fluid therapy as compared to conventional fluid therapy on changes in renal functions among patients undergoing major abdominal or gynaecological surgeries.

The study was randomised, single blind, pragmatic trial, with patients randomly assigned to either Restrictive or Conventional fluid groups. Baseline observation (HR, BP, Spo_2, ECG) were recorded on arrival of patient in 0T, after adequate pre-oxygenation, general anaesthesia was induced with Fentanyl 2 mcg/kg, Propofol 1-2 mg/kg, and Vecuronium 0.10 mg/kg and was intubated using proper size of endotracheal tube (ET tube) and put on intermittent positive pressure ventilation with tidal volume 7-10 ml/kg, sevoflurane was used for maintenance anaesthesia.

Advanced monitoring techniques, such as pulse pressure variation (PPV), central venous pressure (CVP) monitoring, and invasive blood pressure were used to identify fluid responsiveness.

Patients who required urgent or time-critical surgery, with ASA physical status 5, Chronic renal failure requiring dialysis, Liver resection and Minor or intermediate surgery were excluded from study.

There was increased risk of postoperative complications in patients with more than 70 years age, history of coronary artery disease, heart failure, diabetes currently treated with an oral hypoglycaemic agent and/or insulin , preoperative serum creatinine > 200 μmol/L (> 2.8 mg/dL), morbid obesity (body mass index [BMI] ≥35 kg/m2), preoperative serum albumin < 30 g/L and anaerobic threshold (if performed) < 12 mL/kg/min. or two or more of the following risk factors: American Society of Anaesthesiologists (ASA) physical status 3 or 4, chronic respiratory disease, obesity (BMI 30–35 kg/m2), aortic or peripheral vascular disease. Preoperative haemoglobin <100 g/L, preoperative serum creatinine 150–199 μmol/L (>1.7 mg/dL) and anaerobic threshold (if performed) 12–14 mL/kg/min.

The study groups were divided as Conventional ('traditional practice') intravenous fluid group administered balanced salt solution as 10 mL/kg bolus followed by 8 mL/kg/hour as infusion until the end of surgery. A maintenance infusion was then continued at 1.5 mL/kg/hour, for at least 24 hours which was manipulated according to blood pressure.

The restrictive group fluid regimen administered intravenous fluid bolus limited to ≤5 mL/kg at induction. Balanced salt crystalloid at 5 mL/kg/hour as infusion was administered until the end of surgery, and bolus colloid/blood was used intraoperatively to replace blood loss (mL for mL); then a postoperative infusion rate of 0.8 mL/kg/hour until cessation of intravenous fluid therapy within 24 hours.

Required approval from institutional ethical committee of University was taken. Informed written consent after detailed preanaesthetic check-up was taken. The data was analysed using IBM Statistical Package for Social Sciences, version 21.0. Chi-square test was used for qualitative and Independent samples't'-test was used for continuous data. Within group changes in study parameters between pre- and post-operative intervals were assessed using Paired't'-test. The confidence level of the study was kept at 95% and a 'p' value less than 0.05 indicating probability of chance error to be 5% was considered statistically significant. Study data was collected in a paper-based case report form, for subsequent transcription onto an excel database. Data monitoring for integrity, review and interpretation of accruing data, and ensuring the safety of the trial participants was done on a regular basis.

Results

75% of patients in the study were aged between 31 and 60 years, only 5 % of patients were aged <20 years and 13.3% were aged >60 years. Mean age of patients was 47.33 ± 14.07 years. In conventional therapy group, 80 % patients were in age range 31-60 years as compared to 76.7% in restrictive group. However on comparison, both the groups didn't achieve statistical significance.

Majority of patients in Conventional therapy group were females (70%) whereas in restricted therapy group the distribution was equal. The overall sex ratio was 0.67:1. Though proportion of females was higher in conventional therapy group as compared to that in restricted therapy group yet this difference was not significant statistically.

Body weight of patients in conventional therapy group ranged from 38 to 75 kg while height of patients ranged from 151 to 178 cm while in restrictive group weight of patients ranged from 43 to 86 kg while height of patients ranged from 148 to 176 cm. The difference between two groups was not statistically significant for both weight and height.

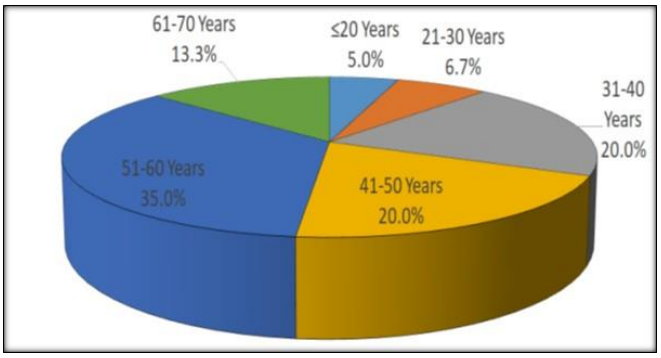

Figure 1: Age Distribution of Study Population

Body mass index ranged from 15.15 to 26.31kg/m² in conventional group, none of the patients in conventional therapy group were obese. In restrictive group 80% were in normal weight category followed by underweight (10%), overweight (6.7%) and obese (3.3%). Overall, Body mass index (BMI) ranged from 15.15 to 31.59 kg/m2.

Mean BMI of patients in restricted therapy group was slightly higher than that of

Conventional therapy group patients, however, on comparing the data statistically, the difference between two groups was not found to be significant.

91.3% patients enrolled in the study had ASA Grade I while 8.3% patients had ASA Grade II, although proportion of ASA grade II patients was slightly higher in restricted therapy group (10%) as compared to that in conventional therapy group (6.7%), but on comparison statistical significance was not achieved.

80% procedures were abdominal surgeries while only 20% were gynaecological surgeries in both the groups and two groups were perfectly matched for type of procedure (p=1).

Mean blood urea levels at pre-operative and post-operative time intervals were 25.62± 8.40 and 24.27± 9.77 mg/dl respectively in conventional therapy group as compared to 22.58 ±7.68 and 24.11 ±6.90 mg/dl respectively in restricted therapy group. Conventional group had higher mean values on comparison with Restrictive fluid therapy but the level of statistical significance was not achieved. Mean change in blood urea levels was -1.35±7.21 mg/dl in conventional therapy and -1.53±8.00 mg/dl in restricted therapy group but there was no significant difference between two groups with respect to change in mean blood urea levels.

Preoperatively, mean serum creatinine level was higher in conventional therapy group than restricted therapy group but in postoperative period it was reverse. There was a decline of 29.2% in mean value in conventional group during postoperative period although restrictive group demonstrated a nominal increase of 1.5% in mean serum creatinine values of postoperative values, but on comparison amongst both the groups the difference was not significant statistically.

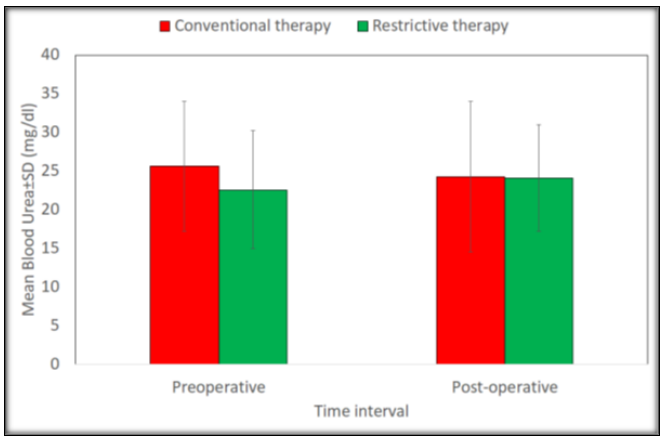

Figure 2: Comparison of preoperative and postoperative blood urea levels and its change during the period between two groups (mg/dl)

Mean serum cystatin C level was similar in both the groups in preoperative period, but during postoperative period restricted group showed higher mean values and on comparison both the groups showed statistical significance. There was increase of 63% in mean value in conventional group during postoperative period and restrictive group demonstrated a increase of 74 % in mean serum cystatin C values of postoperative values. Statistical significance was achieved on comparison of the change in serum cystatin C level from preoperative to postoperative period between two groups.

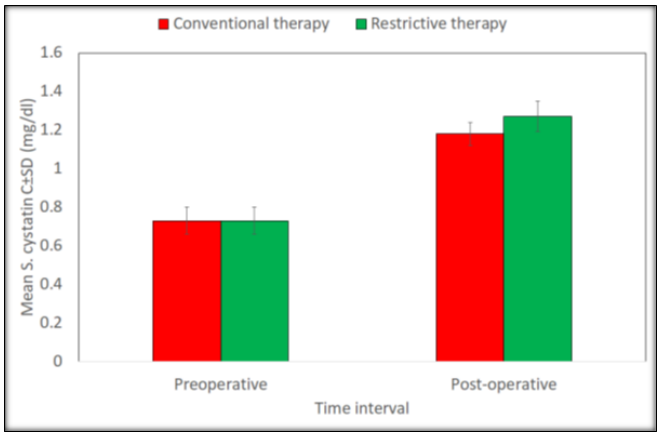

Figure 3: Comparison of preoperative and postoperative Serum cystatin C level and its change during the period between two groups (mg/dl)

Restrictive group showed higher mean serum sodium level in preoperative period but during postoperative period Conventional group demonstrated higher mean sodium values although comparison of changes in both groups did not showed statistical significance.

Restrictive group showed higher mean serum potassium level in preoperative period but during postoperative period Conventional group demonstrated higher mean potassium values although comparison of changes in both groups during both the intervals did not showed statistical significance. There was a decline of 6.5% in mean change in serum potassium level between preoperative and postoperative periods value in conventional group and it was significant statistically although restrictive group demonstrated a decline of 10 % which was significant statistically. On comparing the change in serum potassium level from preoperative to postoperative period between two groups, the difference was not significant statistically.

Restrictive group showed higher mean serum chloride level in preoperative period but during postoperative period Conventional group demonstrated higher mean chloride values although comparison of changes in both groups during both the intervals did not showed statistical significance. There was increase of 2.3% in mean change in serum potassium level between preoperative and postoperative periods value in conventional group although restrictive group demonstrated a minor increase of 0.4 % and both were not significant statistically.

Table 1: Comparison of preoperative and postoperative eGFR (C&G) and its change during the period between two groups

Interval	Conventional Group (n=30)	Restricted Group(n=30)
Preoperative	95.60 ± 53.14	110.00 ± 32.14
Post operative	113.14 ± 50.56	110.08 ± 38.37
Change	17.54 ± 47.95	0.08 ± 32.99

Preoperatively Mean eGFR level was higher in restrictive group, but during postoperative period Conventional group demonstrated higher Mean eGFR level but without any statistical significance on comparison of both groups. There was a mean % decline of 15.2% in eGFR level between preoperative and postoperative periods of conventional group while restrictive group had decrease of 26.9%. Both the groups achieved statistical significance on comparing preoperative and postoperative values.

In present study, there was no adverse effect observed due of fluid therapy giving rise to infectious, pulmonary, cardiac, gastrointestinal or renal complications in either of two groups and neither any post-operative mortality in two groups.

Table 2: Comparison of preoperative and postoperative eGFR (based on CKD-EPI creatinine and cystatin formula) and its change during the period between two groups

Interval	Conventional Group (n=30)	Restricted Group(n=30)
Preoperative	113.03 ± 37.38	123.95 ± 19.38
Post operative	95.90 ± 25.90	90.55 ± 19.13
Change	-17.13 ± 25.90	-33.40 ± 17.35

Discussion

Perioperative fluid therapy helps in maintenance or correction of fluid balance to prevent dehydration or Hypovolemia, ensures adequate circulation by using vasoactive and/or cardioactive substance and provides adequate oxygen delivery to organs. It maintains plasma composition by balancing the electrolytes.

Plasma osmolality is maintained by dynamic changes in kidneys through water excretion as a response to fluid intake. Restricted fluid therapy produces concentrated urine to reduce availability of water. Osmotic gradient is created and maintained by kidneys which become increasingly concentrated from the cortex to the medulla. The loops of Henle and collecting ducts in a counter-current fashion maintain the renal osmotic gradient which allows for reabsorption of the majority of water that passes through the kidney.[6,7]

An adverse renal outcome of acute kidney injury depends on dose, type (colloid vs. crystalloid) as well as balancing of crystalloids and colloids**.** Estimation of fluid requirements is adequately provided by pulse pressure variation, stroke volume variation, or other dynamic measures of fluid responsiveness.[8,9]

Liberal fluid administration can result in alveolar capillary edema thereby affecting the renal function adversely by impairing the gas exchange and causing acid-base imbalance whereas moderate restriction in administration of fluid volumes provides better outcomes of renal parameters.[10]

Restrictive fluid therapy in abdominal surgery patients is associated with faster return of bowel function, fewer complications and shorter hospital stay.[11]

Patient Profile

RELIEF trial that included 3000 patients who underwent major abdominal surgeries and included patients with an expected operative duration of at least 2 hours, an expected hospital stay of at least 3 days and presence of increased risk of complications,

Sahmeddini et al, [12] on the other had conducted their study on a study population with mean age 26.4 years and predominantly male (64.2%) undergoing liver transplant

surgery, thus showing that despite the younger age of patients they had patients with a specific high-risk more complicated surgery

Sujatha et al and Cesur et al in their study despite having the mean age of patients to be 5 to 15 years older than our study and having a male dominance had included only patients of ASA I/II as in present study. [13,14]

Compared to all these studies, the patients in present study had a better surgical grade and hence lower post-operative complication risk.

Pre-operative Demographic and Clinical Matching

In present study, no statistically significant difference between two groups was observed for age, gender, BMI, grade and type of surgery and renal functions.

Preoperative Kidney Function Profile

Mean blood urea, serum creatinine and serum cystatin C levels were the primary renal functions assessed apart from electrolytes Na+, K+ and Cl-measured in the pre-intervention period. There was no statistically significant difference between two groups for these primary renal function outcomes and electrolyte levels prior to surgery.

Cystatin C has been recognized as an early marker of impaired renal function and acute kidney injury in a number of clinical situations. [15–17] Cystatin C is a non-glycosylated protein that demonstrates cysteine proteinase inhibitor activity. It has been shown to have a constant rate of production by all nucleated cells and serum cystatin C levels are found to reciprocate the changes in glomerular function rate. [16] Hence, estimation of serum cystatin C levels is considered to give a better estimate of kidney function. [18]

Our findings are in agreement to the previous studies by Kumar et al who also reported similar mean creatinine values. [19] Although Cesur et al reported lower median pre-operative creatinine levels while Alimian et al reported a higher preoperative mean blood urea and serum creatinine levels as compared to the present study. [14,20]

Glomerular function rate was estimated by 2 methods in the present study. The first method used by us was based on Serum creatinine as the basis of calculation (C&G formula) and second method used by us was based on combination of serum creatinine and serum cystatin C levels. [21] Pre-intervention estimated GFR values based on C&G formula and CKD-EPI formula based on Cystatin C and S. creatinine were lower in conventional group n comparison with restrictive group**.** Alimian et al reported a higher GFR indicating a better preoperative renal function as compared to that in present study. [20]

Post-operative Renal Functions

Post-operatively, mean serum urea, creatinine were comparable in both the groups in our study. Although serum cystatin c levels were observed to be higher in restrictive group and there was statistically significant difference between two groups for cystatin C levels.

In our study, mean values of electrolytes Na+, K+ and Cl-levels were observed to be higher in conventional group, although there was no statistical significant difference in post-fluid therapy electrolyte levels between two groups.

Estimated GFR values based on C&G formula and CKD-EPI formula based on Cystatin C and S. creatinine were observed to be higher in conventional group but this didn't achieved statistical significance on comparison between two groups.

Raised cystatin C levels are indicators of impaired renal function and an early marker of acute kidney injury. [15] In our study, Serum Cystatin C levels were observed to be higher in restrictive therapy as compared to conventional therapy group and thus indicated a higher risk of AKI to be associated with restrictive therapy. Myles et al. [1] reported a higher incidence of AKI in restrictive therapy group (8.6%) as compared to that in conventional therapy group (5%), although there was no incidence of AKI due to Inclusion of patients with relatively better grade of surgery (ASA grade) in present study which reduced the rate of adverse renal outcomes like AKI. Shin et al, [10] reported the lower incidence of AKI with less fluid administration.

Cystatin C definitely is a better early indicator of acute kidney injury as compared to serum creatinine and other renal function parameters studied and thus in a study population where risk of AKI is low, sensitive markers like Cystatin C as used in present study should be used more frequently to evaluate the impact of fluid therapy on renal function outcomes.

Our findings are similar to the previous study by Alimian et al, [20] who also failed to find a significant difference in post-operative GFR with respect to estimated GFR calculated using C & G formula based on serum creatinine and CKD-EPI formula based on combination of serum creatinine and Cystatin C levels between restricted and liberal fluid therapy groups.

Evaluation of Change in Renal Function Parameters

In our study**,** significant increase in cystatin levels, a significant decline in serum potassium levels and in GFR (as per CKD-EPI formula based on combination of Cystatin C and Creatinine levels) was observed in both the groups. Alimian et al, [20] found a significant decline in blood urea levels in both the groups, a significant decline in creatinine levels and a significant increase GFR in liberal fluid therapy group only. Cesur et al, [14] observed a significant decline in serum potassium and serum albumin levels and a significant increase in chloride levels in both the groups.

Adverse Events/Complications

In present study there were no complications of infections, pulmonary, cardiac, gastrointestinal or renal in either of two groups and neither any post-operative mortality in two groups. Although Myles et al, [1] in their study reported mortality in 6.4% of patients in both the groups and surgical site infection and sepsis in 16.5% and 10.6% of restrictive therapy and 13.6% and 8.7% of liberal therapy groups, thereby depicting increase of post-operative complications in restrictive group.

Conclusion

Correlation of renal function parameters is required to assign the correct use of intravenous fluids in perioperative period for better patient outcome although in our study, liberal or conventional fluid therapy seems to have an edge over restricted fluid therapy.

Our results point to the need for a more extensive and elaborated study to evaluate the potential prognostic significance of need to carry out further studies in patients with different surgical risk profiles and inclusion of more variables that could determine the outcome along with impact of type of fluid therapy in duration of hospitalization and post-operative survival and morbidity in long term also needs a consideration in further studies

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