Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i4.5336

COLLOIDS VERSUS CRYSTALLOIDS GUIDED BY INFERIOR VENA CAVA COLLAPSIBILITY INDEX IN BIPOLAR TRANSURETHRAL RESECTION PROSTATE; RANDOMIZED CONTROLLED STUDY.

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Abstract

Background: Intravenous (IV) fluid replacement during transurethral resection of the prostate (TURP) is still unclear. The purpose of this study was to compare colloids versus crystalloids using inferior vena cava collapsibility index (IVC-CI) to show their impact on the total amount of IV infused fluids.

Methods: This study included 34 American Society of Anesthesiologists physical status class I and II patients who underwent bipolar TURP. Eligible patients were randomly assigned to two equal groups, crystalloid and colloid (n=17 in each group). The study subjects and the investigators assessing the outcome were blinded to the study group. The primary outcome was the total IV administered fluids volume. Secondary outcomes were the postoperative serum sodium and potassium, maximum and minimum IVC diameters, IVC-CI, incidence of bradycardia and hypotension, and total IV furosemide dose

Results: The mean ± SD of the total intravenous infused fluids in colloid group was 355.6 + 151 ml and in the crystalloid group was 602.5 + 200 ml (p = 0.0003). There were no statistical difference between the 2 groups in the serum sodium and potassium at the end of surgery, maximum and minimum IVC diameters, IVC-CI, incidence of bradycardia, incidence of hypotension, total intraoperative ephedrine dose, incidence of intraoperative nausea and/or vomiting, and total IV furosemide dose.

Conclusions: Colloid volume optimization using US-guided IVC-CI had reduced the total IV fluid volume and achieved volume optimization during TURP surgery with hemodynamic stability preventing fluid overload.

Key words: Transurethral resection prostate, volume overload, colloids, crystalloids, inferior vena cava diameter, fluid challenge. (https://clinicaltrials.gov/ct2/show/NCT04131361)

Introduction

Transurethral resection of prostate (TURP) is commonly associated with complications such as TUR syndrome, bleeding, myocardial ischemia, hypothermia, prostatic capsular perforation, bladder or urethral perforation and postoperative cognitive impairment.[1]

The TUR syndrome is a common complication caused by excessive irrigating fluid absorption into the circulation, resulting in acute changes in intravascular volume, plasma solute concentrations, and osmolality. The severity of the symptoms is proportional to the amount of irrigating fluid absorbed. Irrigation fluid is absorbed at a rate of 10 to 30 ml per minute of operating time. Five to twenty percent of patients will absorb more than one litre.[2]

Volume changes have the greatest impact on the cardiovascular system. Rapid absorption of a significant amount of irrigation fluid can result in hypertension with reflex bradycardia, as well as acute cardiac failure and pulmonary oedema.[2] The central nervous system (CNS) is primarily affected by acute changes in plasma sodium content and osmolality. In CNS disturbances, hypoosmolality is of greater importance than hyponatraemia..[3]

Several new procedures, including laser ablation, laser enucleation, photoselective vaporization, and bipolar resection in saline, may be an effective surgical option for preventing this complication, particularly in critically ill patients. The use of sodium chloride solution for irrigation in bipolar TURP (B-TURP) has also almost eliminated the possibility of neurological symptoms of TUR syndrome. [4]

Normal saline absorption, however, has been linked to hyperchloremic metabolic acidosis and volume overload in the HoLEP. [5-6-7]

Colloids have a lower volume of distribution than crystalloid solutions, therefore less fluid and time are required for correcting intravascular volume deficits. It has also been demonstrated that colloids increase oxygen transfer, myocardial contractility, cardiac output, and tissue oxygenation.[8]

Monitoring the IVC diameter and respiratory variability is frequently used to determine fluid responsiveness and volume loading status.[9] IVC characteristics, including diameters and collapsibility indices, may be assessed and quantified quickly at the bedside and have shown an excellent correlation with RAP.[10]

Intravenous fluid replacement during TURP remains questionable. Recently, ultrasonography of the inferior vena cava (IVC) has been utilized to monitor volume status and predict fluid responsiveness. The purpose of this study was to test a new strategy based on a preventive target by determining the IVC collapsibility index (CI) and strictly infusing intraoperative replacement fluids on and off depending on the IVC-CI while comparing colloids vs crystalloids..

The goal of this study was to compare colloid and crystalloid to reduce fluid overload and volume optimization during TURP surgery with hemodynamic stability relying on US-guided IVC-CI. We hypothesized that inravenous infusion of colloid solutions to obtimize the volume status using US-guided IVC-CI would reduce total IV fluid volume by accommodating the transurethral inevitable absorption of the currently used irrigation crystalloid fluid (saline 0.9%) that was accidentally absorbed, and converting it from a circulatory overload to a complementary part of the replacement IV fluids, preventing fluid overload and TUR syndrome.

Materials and methods

This randomized double-blinded controlled trial was carried out in Mansoura Urology and Nephrology Center (UNC) from November 2019 to March 2022 after getting approval from Institutional Review Board (IRB) (R.19.10.644) , Mansoura Faculty of Medicine. It was registered before subject enrollment at ClinicalTrials.gov (https://clinicaltrials.gov/ct2/show/NCT04131361) ;

principal investigator: M.A.G.; date of registration: October 12, 2019). A consent, which was written and informed was obtained from all subjects in the study. This study was conducted in compliance with the ethical principles of the Declaration of Helsinki (2013) and is presented in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

The inclusion criteria were American Society of Anesthesiologists (ASA) physical status class I-II male patient aged 40-80 years old subjected to transurethral endoscopic resection of the prostate (TURP) (Bipolar TURP using saline 0.9% as an irrigating fluid), Only patients with prostate volume from 45-100 gm (measured preoperatively by transrectal ultrasound (TRUS)) were included in this study. Exclusion criteria were height <150 cm, weight <55 kg, contraindications to spinal anesthesia (increased intracranial pressure or local skin infection), uncontrolled diabetes mellitus, cardiovascular failure, cerebrovascular uncontrolled deficit, or other renal disease, hemoglobin level <10 gm/dL, International Normalized Ratio (INR) >1.4, Platelet count <100,000 /mm3, and preoperative serum creatinine >1.5 mg/dL.

Eligible patients were randomly assigned to two equal groups (n=17 in each group) according to a computer-generated table of random numbers. Group (A) was a crystalloid group and Group (B) was a colloid group. Allocation was concealed in sequentially numbered, sealed opaque envelopes that were opened only after obtaining the consent and recording all the baseline data. The study subjects and the investigators assessing the outcome were blinded to the study group. The second investigator (M.A.G.) assessed the patients for eligibility, obtained written informed consent, opened the sealed opaque envelopes containing group allocation, and administered the specific study solutions. All study solutions were 500 mL bottles wrapped with opaque plastic covering prepared by a nurse anesthesiologist not involved in the study to blind the outcome assessors and the patients. The investigators (M.A.T.) and (A.H.E) recorded the baseline systolic BP and heart rate, obtained the baseline IVC image, and recorded the intraoperative and outcome data (IV fluids, incidence of bradycardia, incidence of hypotension, IVC images, serum sodium and potassium at the end of surgery, the total furosemide dose, ephedrine requirement, and incidence of intraoperative nausea and or vomiting).

All patients were assessed with routine investigations including complete blood picture(CBC), serum aspartate transaminase (AST) and alanine transaminase (ALT), serum creatinine, serum sodium and potassium levels, international normalized ratio (INR), electrocardiography (ECG).

Spinal anesthesia was performed under strict aseptic technique in the sitting position at the L2-L3 or L3-L45 interspace using 25-gauge spinal needle with the standard monitors for heart rate, non invasive blood pressure, ECG, and pulse oximetry were attached. Bupivacaine 12.5 mg (2.5 mL 0.5%) then dexmedetomidine 10 μg were administered in the subarachnoid space. Surgery started after attaining an upper sensory level of T10 or higher tested by pin prick. Then the patient was positioned in lithotomy posture.

Bipolar TURP was started with warm saline 0.9% irrigation fluid, keeping the irrigation fluid column at a height of 60 cm, measured from the level of pubic symphysis of the patients on the operating table. All patients received maintenance fluid with the rate 1 ml/kg/h of Ringer acetate solution throughover the surgery. All the IVC images were obtained by two investigators who had performed >200 cases in a similar manner before starting the study, using the technique described by the American Society of Echocardiography. The IVC was scanned in the long axis using an 8-2 MHz curved array transducer placed longitudinally in the subcostal region. The maximum and minimum IVC diameters occurring in a single respiratory cycle were measured using the M-mode by asking the patient to take a smooth deep inspiration and we tried to standardize this deep breath at every measurement of the IVC diameters. The measurements were about 2 cm proximal (caudal) to the ostium of the right atrium and immediately proximal to the junction with the hepatic veins.[10]

The IVC collapsibility index (IVC-CI) was calculated using the following formula: IVC-CI = (maximum IVC diameter – minimum IVC diameter)/maximum IVC diameter, expressed as percentage. When obtaining the images intraoperatively, the investigator was separated from the surgical field by a sterile drape, and the ultrasound probe was covered with a sterile cover. IVC

diameter and collapsibility index were recorded at baseline and then every 30 minutes till the end of surgery. Fluid bolus was administered over 15 minutes, then we checked the response after 15 minutes which is the time of the next measurement.

Fluid administration regime (either Ringer acetate or 6% hydroxyethyl starch 130/0.4 in 0.9% sodium chloride (voluven®) depended on the percentage of IVC-CI as follow:

If the basal IVC-CI was < 40%, no fluids were given except the maintenance fluids until the next reading after 30 minutes. In the next IVC-CI readings, if they were more than or equal 50%, a bolus of 150 ml of the fluid was given over 10 minutes aiming to reach IVC-CI in the range of 40%-50%. At any time the IVC-CI reading was < 30%, beside administering no fluids, loop diuretic (furosemide) 10 mg was given and the reading was repeated after 10 minutes.

Ephedrine 3, 5, and 10 mg IV boluses were administered when the systolic blood pressure decreased below 90% (mild hypotension), 80% (moderate hypotension), and 70% (severe hypotension) of the basal line. Atropine 0.5 mg IV is given when bradycardia occurs (heart rate < 50 beats /minute).

The primary outcome was the total IV administered fluids volume. Secondary outcomes were the postoperative serum sodium and potassium, maximum and minimum IVC diameters (baseline and every 30 minutes till the end of surgery). IVC-CI (baseline and every 30 minutes till the end of surgery), incidence of bradycardia, incidence of hypotension, total intraoperative ephedrine dose, incidence of intraoperative nausea and/or vomiting, and total IV furosemide dose.

Statistical analysis

The collected data were analyzed using the SPSS program (version 22). Normality of numerical data distribution was tested by Kolmogorov-Smirnov test. Normally distributed numerical data were presented as mean + standard deviation and compared in different groups using unpaired student's t test. Non-normally distributed numerical data were presented as median (range) and compared non-parametrically using Mann-Whitney U test. Categorical data were presented as number (percentage) and their comparison was performed using Chi-square test. All data were considered statistically significant if P value was ≤ 0.05.

A Priori analysis was done to estimate the study sample size which was based on previous study [11] using total IV fluid volume as a study primary outcome. The priori study was done on 10 subjects using crystalloid solution; the mean ± standard deviation of the total IV fluid volume was 577 + 75 mL. Assuming α error = 0.05, Power (1-β error = 0.95), a sample size of 15 patients were needed in each group to detect a 250 mL difference between groups, which was considered the least clinically significant effect. 10% increase was added for the dropouts reaching a total sample size of 34 patients with 17 patients for each of the study groups.

Results

From November 2019 to March 2022, 40 patients were assessed for eligibility in the current study; six patients were excluded and the remaining 34 patients who met the inclusion criteria were enrolled and analyzed. ***(*Figure 1*)***.

Patients in the two studied groups were comparable with respect to the demographic data and the baseline data. (P > 0.05) ***(Table 1)***.

The mean ± SD of the total IV infused fluids in the colloid group was 355.6 + 151 ml which was significantly lower than that in the crystalloid group which was 602.5 + 200 ml (p = 0.0003). (***Table 2).***

There were no statistical difference between the 2 groups in the serum sodium and potassium at the end of surgery, incidence of bradycardia, incidence of hypotension, total intraoperative ephedrine dose, incidence of intraoperative nausea and/or vomiting, and total IV furosemide dose. (***Table 2)***

Serial changes of the systolic BP were analyzed. Hypotension had occurred more in the crystalloid group, but was non-significant. ***(*Figures *2&3)***.

Serial changes of values of maximum and minimum IVC diameters and IVC-CI were analyzed. (***Tables 3, 4, 5 and* Figures *4, 5, 6)***. In the colloid group, despite not being significant, the maximum

and minimum IVC diameters increased at each time point compared to the crystalloid group, also the IVC-CI did not significantly change at any time point compared to the crystalloid group but still lower in the colloid group.

Discussion

This randomized controlled trial found that IV administration of colloids (hydroxyethyl starch 130/0.4 (HES)) as a replacement therapy guided by ultrasound measurement of IVC-CI reduced total IV fluid volume compared to crystalloids (Ringer's acetate) in patients undergoing TURP in 0.9% saline under spinal anesthesia. There was no significant difference between the two groups in hemodynamics, preoperative and postoperative serum sodium and potassium levels, values of the maximum and minimum diameters of IVC and IVC-CI, total IV furosemide dose, and incidence of nausea and vomiting.

The majority of research comparing colloids and crystalloids in goal directed fluid therapy were conducted on patients having major surgical procedures or critically ill patients, and the majority of them were carried out by stroke volume (SV) optimization. However, few studies were guided by IVC-CI measurement for volume status optimization, and almost no studies were conducted on TURP patients. According to volume pharmacokinetic models, the administered colloid solution enters the intravascular compartment and remains there for an extended period, causing it to expand. Colloids also raise the osmotic gradient between the intravascular compartment and the interstitium, enabling plasma volume preservation and, to a lesser extent, limiting the development of interstitial edema. Crystalloid solution, on the other hand, is initially diffused into the intravascular compartment and subsequently redistributed to the interstitial compartment within 20-30 minutes.These modifications may explain why, when compared to crystalloids, IV administration of colloids guided by ultrasound measurement of IVC-CI lowered total IV fluid volume, and colloid solutions remained in circulation for a longer period of time.Lindroos et al [12] investigated the efficacy of stroke volume guided administration of HES solution over Ringer's acetate solution in neurosurgical patients. They discovered that the mean ± SD dosages of HES vs Ringer's solution after 30 minutes of placement were 343 ± 94 mL and 450 mL ± 156 mL (P = 0.036), respectively, and at the end of surgery were 464 ±284 mL and 707±425 mL (P = 0.087). Joosten et al [13] conducted another study in which they compared the efficacy of crystalloids versus colloids for intraoperative goal-directed fluid therapy utilizing a closed-loop device. In the protocol, one hundred and sixty patients were randomized. Using a stroke volume and stroke volume variation monitor, a closed-loop system administered 100-ml fluid boluses according to a specified goal-directed strategy.The incidence of postoperative complications, total volume of fluid administered intraoperatively, and the net fluid balance were significantly lower in the colloid group.

According to the present study, hypotension had occurred more in the crystalloid group, but was non-significant. These patients needed more fluid, and even when optimized, they still needed ephedrine to achieve the desired blood pressure. Park et al [14] compared the incidence of post-spinal anesthesia induced hypotension in women receiving either colloid or crystalloid coloading under prophylactic phenylephrine infusion; they revealed that the incidence of hypotension was lower in the colloid group, but insignificantly compared to the crystalloid group, with no significant difference in the number of hypotensive patients between the two groups.Ultrasound measurements of IVC diameters and IVC-CI provide a dependable noninvasive tool for assessing right atrial pressure [15], predicting fluid responsiveness in critically ill patients [16], predicting hypotension after general anesthesia induction [17], and guiding intraoperative fluid and vasopressor management in high-risk patients [18]. An IVC-CI of more than 40% or (42% in separate studies) could predict fluid responsiveness with conflicting outcomes in spontaneously breathing persons. According to one study, an IVC-CI greater than 40% was associated with fluid responsiveness, however an IVC-CI less than 40% or 42% did not rule out fluid demands.[19] According to a recent meta-analysis [20], the IVC diameter variation with respiration to predict volume responsiveness is more reliable in mechanically ventilated patients than in spontaneously breathing individuals.It was hypothesized that the reduced sensitivity

with spontaneous breathing was related to shallow, nonstandardized breathing. However, using deep standardized inspiration improved the sensitivity and specificity of IVC ultrasound to predict volume responsiveness (pooled sensitivity 87%, pooled specificity 89%) in 146 spontaneously breathing patients from one prospective study [21].The effect of crystalloid and colloid on IVC-CI and diameters did not change significantly during the procedure, according to our findings. Infusing an iso-oncotic colloid has a volume expansion effect comparable to that of a crystalloid fluid. The degree of similarity will be determined by the degree of endothelial glycocalyx shedding, endothelial glycocalyx permeability, pre-infusion volume status, infusion rate, and degree of vasoconstriction [22]. This could explain why, in large clinical trials of critically ill patients, the volume expanding effects of colloids were significantly lower than expected. The Crystalloid vs Hydroxyethyl Starch Trial (CHEST) [23] and the Saline versus Albumin Fluid Evaluation (SAFE) [24] are two examples. clinical trials, the observed ratio of colloid to crystalloid to achieve the same hemodynamic resuscitation end-points was 1:1.3 and 1:1.4 respectively, which is markedly different to the ratio of 1:3–1:5 predicted by the classical Starling principle.Several aspects should be addressed. First, we used tetrastarch solutions as a colloid replacement fluids because it is still used in our institution. Alternatively, we tried to use human albumin instead of HES but the available amount was not sufficient for all patints due to current shortage. Second, we excluded patients with a height <150 cm or body weight < 60 kg because they may require modification in the intrathecal dose of a local anesthetic drug or may affect the incidence of hypotension, or ephedrine doses. Third, prostate volumes of 45-100 gm were included in the study because beyond these limits, the rate of absorption of the irrigating fluid would vary largely depending on the duration of resection which is directly proportional to the gland size. Fourth, we excluded patients with preoperative serum creatinine > 1.5 mg/dl. Despite being a surgical patient who is typically given smaller amounts of low molecular weight synthetic colloids over just a few hours, there is a dose-dependent renal toxicity associated with these fluids in patients having noncardiac surgery. Fifth, dexmedetomidine was administered intrathecally as an adjunct to the local anesthetic to maintain a longer duration of sensory block to cover the variable duration of the surgery. Although not FDA approved for intrathecal administration, we used it in this study because it is commonly used in our institution.

Recommendations

Future studies in this area better focus on the development of broad goal directed strategies in perioperative fluid therapy beside finding the best type of fluids. Furthermore, because of the potential ability of IVC-CI to reflect blood volume and non-invasive peculiarity, the studies of IVC-CI use in hemodynamic status and its reliability to predict fluid responses are required to be confirmed in future studies. Also, we recommend using markers for adequate tissue perfusion such as serum lactate level and using rotational thromboelastometry (ROTEM) to assess coagulation haemostasis for complete accurate comparison between crystalloids and colloids.

Conclusion

Both crystalloids or colloids solutions could be used for fluid replacement during bipolar TURP. To decrease the commonly associated complications caused by excessive irrigating fluid absorption into the circulation, these replacement fluid solutions should be administered cautiosly.

The strict colloid administration using US guided IVC-CI had reduced the total IV fluid volume, achieved volume optimization by accommodating the transurethral inevitable absorption of the currently used irrigation crystalloid fluid (saline 0.9%) that was accidentally absorbed, and converting it from a circulatory overload to a complementary part of the replacement IV fluids.

Conflicts of interest. – The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Funding. – The authors report no involvement in the research by the sponsor that could have influenced the outcome of this work.

Authors' contributions. – All authors contributed to the manuscript, read and approved the final version of the manuscript.

Acknowledgements. – Authors acknowledge the Department of Anesthesiology and Intensive Care Medicine for its contribution in helping to recruit patients in this study.
Institutional Review Board (IRB) number: R.19.10.644.

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TABLES

Table 1:Demographic data and baseline values.

	Crystalloid Group n = 17	Colloid group n = 17	P value
Age (years)	69 +7	69.8+ 6.5	0.74
Weight (kg)	75.1 + 10	77.4 + 12	0.36
Height (cm)	169.2 + 4	167.5 +5	0.78
Duration of surgery (minute)	119 + 47	125.5 + 35	0.78
Baseline values			
Systolic blood pressure (mm Hg)	132+ 12	135+ 8	0.51
Heart rate (beats/m)	85+ 9	87+ 5	0.45
Maximum IVC diameter (cm)	1.45 +0.36	1.39 +0.30	0.65
Minimum IVC diameter (cm)	0.72 +0.21	0.82 +0.33	0.52
IVC-CI (%)	44.4+ 20.9	34.5+ 1.7	0.07
Serum sodium (mEq/L)	140.8 + 2.4	140.9 + 2.9	0.86
Serum potassium (mEq/L)	3.9 +0.36	3.9 +0.35	0.83

Values are presented as mean ± SD. Kg, kilogram. cm, centimeter.

Table 2: Patients outcome data.

	Crystalloid Group n = 17	Colloid group n = 17	P value
Total intraoperative IV fluids (ml)	602.5 + 200	355.6 + 151	0.0003*
Total intraoperative ephedrine dose (mg)	6 + 3.2	4.3 + 1.2	0.22
Total furosemide dose(mg)	12.5 + 5	15 + 5	0.42
Intraoperative nausea and/or vomiting	1 (5.9%)	3(17.6%)	0.60
Bradycardia [a]	2 (11.8%)	4(23.5%)	0.65
Hypotension [b]	6 (35.3%)	3 (17.6%)	0.44
Postoperative serum sodium (mEq/L)	141 + 2.5	138.7 + 3.7	0.06
Postoperative serum potassium (mEq/L)	4 +0.40	3.9 +0.26	0.74

Values are presented as mean ± SD or number (%) . [a] HR < 50 beats/minute. [b] Systolic blood pressure <90% of baseline.

Table 3: Intraoperative values of IVC collapsibility index

	Crystalloid Group n = 17	Colloid group n = 17	P value
IVC-CI at 30 min(%)	51.2 + 6	39.8 +13.4	0.83
IVC-CI at 60 min(%)	60.4+ 6	55.1 +20.7	0.40
IVC-CI at 90 min(%)	48.7 +0.9	51.8 +2.2	0.10
IVC-CI at 120 min(%)	66.6 +0 .8	50.9+ 8.1	0.48
IVC-CI at 150 min(%)	52.7 +3.8	52.7 +11.1	0.39
IVC-CI at 180 min(%)	40.6 +4.3	56.6 +10.7	0.16

Values are presented as mean ± SD..IVC, inferior vena cava.CI, collapsibility index.z

Table 4: Intraoperative values of maximum IVC diameters

	Crystalloid Group n = 17	Colloid group n = 17	P value
Max IVC diameter at 30 min(cm)	1.51 +0.37	1.68 + 0.29	0.19
Max IVC diameter at 60 min(cm)	1.55 +0.32	1.62+0.54	0.14
Max IVC diameter at 90 min(cm)	1.85 +0.51	2.09 +0.38	0.35
Max IVC diameter at 120 min(cm)	1.35 +0.21	2.22 +0.43	0.18
Max IVC diameter at 150 min(cm)	1.85 + 0.15	1.95 + 0.17	0.09
Max IVC diameter at 180 min(cm)	1.6 +0.1	2.3+0.63	0.06

Values are presented as mean ± SD..IVC, inferior vena cava. Min, minute. Max, maximum. Cm, centimeter

Table 5: Intraoperative values of minimum IVC diameters

	Crystalloid Group n = 17	Colloid group n = 17	P value
Mini IVC diameter at 30 min(cm)	0.71 +0.17	0.78 +0.14	0.29
Mini IVC diameter at 60 min(cm)	0.85+0.25	0.79 +0.24	0.26
Mini IVC diameter at 90 min(cm)	1.12+0.30	0.92 +0.16	0.09
Mini IVC diameter at 120 min(cm)	1 + 0.14	1.22 + 0.29	0.07
Mini IVC diameter at 150 min(cm)	0.8 +0.1	0.92+0.25	0.82
Min IVC diameter at 180 min(cm)	0.95+ 0.07	0.97+0.15	0.81

Values are presented as mean ± SD..IVC, inferior vena cava. Min, minute. Mini, Minimum. Cm, centimeter

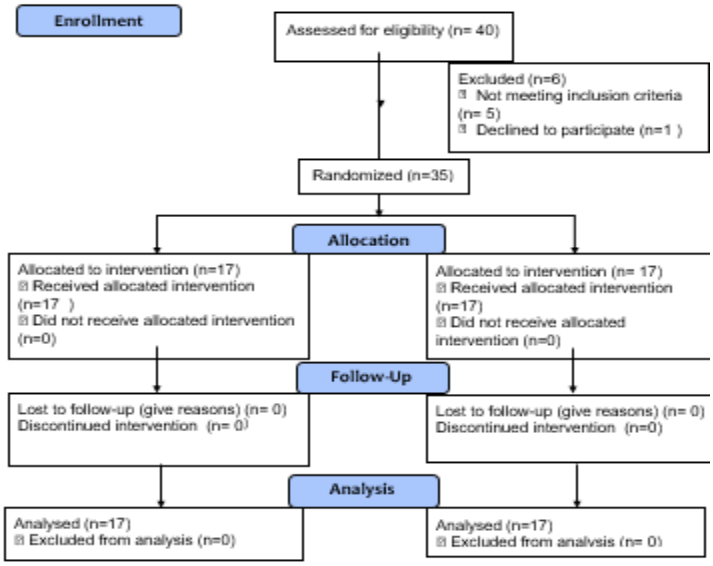

Figure 1 : Study flow chart

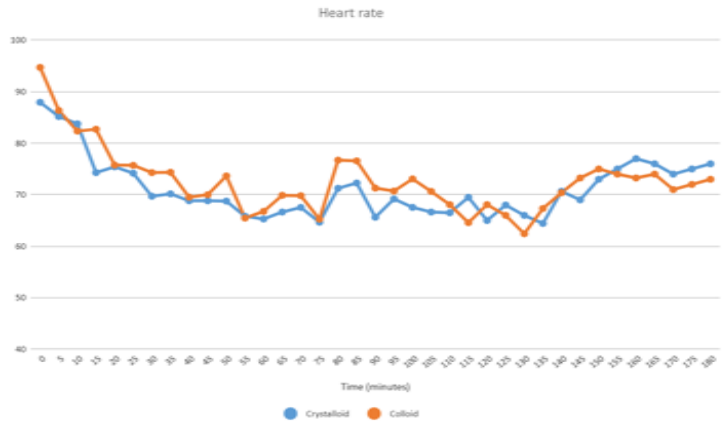

Figure2 : Mean values for perioperative heart rate.

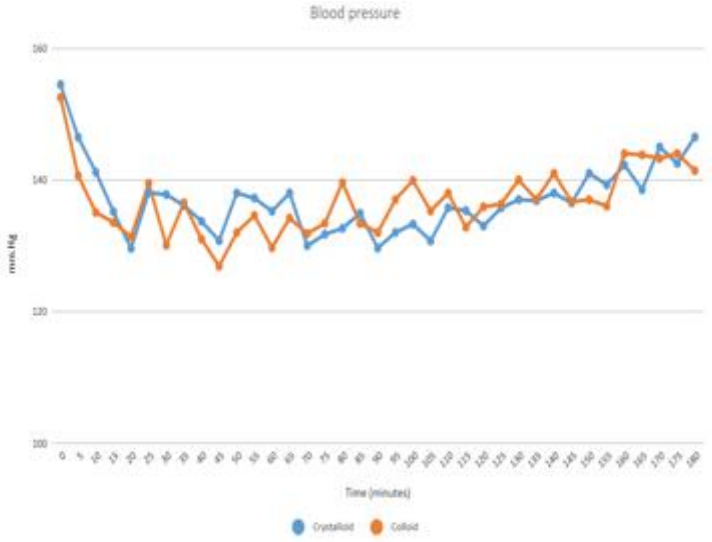

Figure 3: Mean values of perioperative systolic blood pressure.

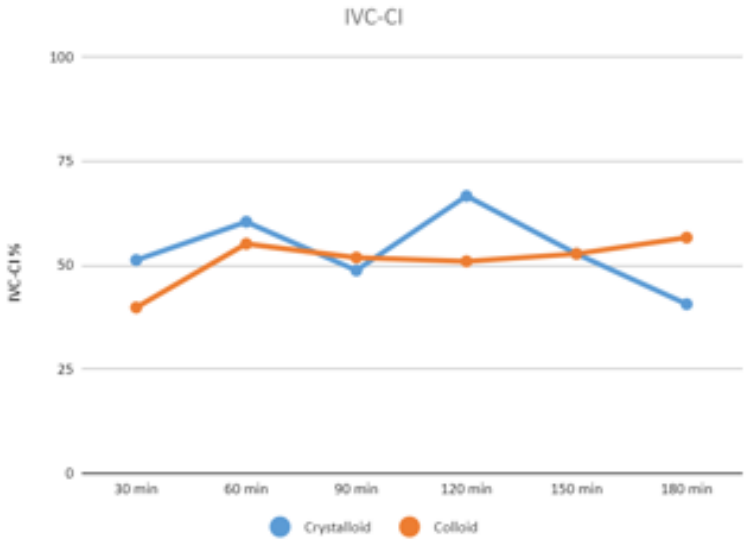

Figure 4: Intraoperative values of inferior vena cava collapsibilty index

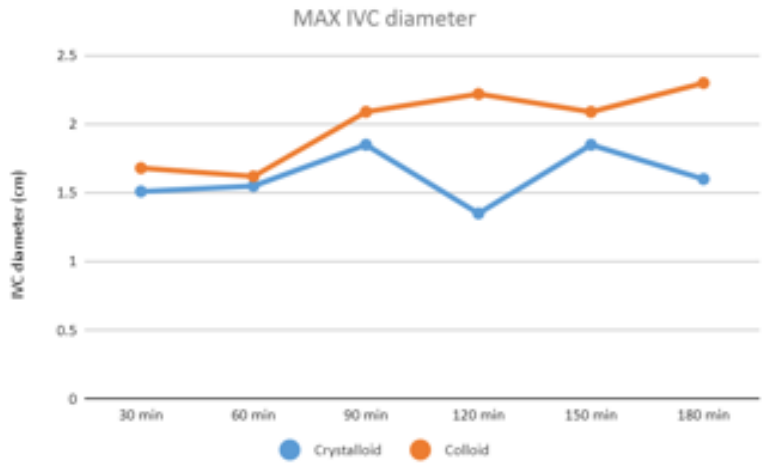

Figure 5: Intraoperative values of maximum inferior vena cava diameters

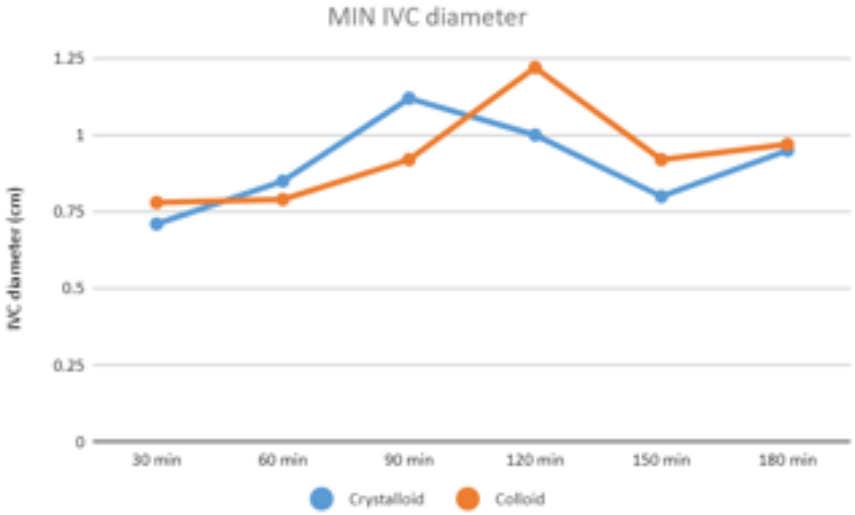

Figure 6: Intaoperative values of minimum inferior vena cava diameters.