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Complications after therapeutic plasma exchange within 24 hours

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ABSTRACT

Background: By therapeutic apheresis is to remove a pathologic element from blood or to modulate cellular function. By this study we observed, complications after the therapeutic plasma exchange (TPE) within 24 hours with respect to patient's demographic profiles and procedural variations.

Methods: One-year prospective observational study conducted by the Department of Transfusion Medicine in collaboration with the Medicine Department, King George's Medical University, Lucknow India.

Results: In our study total of 60 cases and total of 150 TPE cycles were performed. Maximum mean age (36±4) was observed for cough and vomiting both and maximum mean BMI was observed followed for Infection at phlebotomy site (36.34±5.09). Maximum mean variation of hemoglobin was observed for vomiting (2.28±0.00), followed by internal bleeding. Maximum mean variation of activated partial thromboplastin time (aPTT) was observed for cough (22.05±0.34), followed by vomiting. Maximum mean variation of prothrombin time (PT) was observed for hypothermia (13.16±10.47), followed by internal bleeding. Maximum mean variation of S. creatinine was observed for abdominal discomfort (0.23±1.54), followed by vomiting. Maximum mean variation of systolic blood pressure (SBP) was observed for cough (7.00±5.20), followed by bipedal edema. Maximum mean variation of SpO₂ was observed for death.

Conclusions: Complication within 24 hours after the procedure was abdominal discomfort mainly in males with a correlation with body mass index (BMI). We observed significant positive association with complication versus APTT, PT, S. urea, S. creatinine, pulse, SBP, SpO₂ and BMI. This emphasizes the decreasing trend of the complications with the increase in number of cycles.

Keywords: Therapeutic plasma exchange, Fresh frozen plasma, Demographic profile, Delayed complications, Procedural variations

INTRODUCTION

Apheresis (plural aphereses; from the ancient Greek aphaire-sis, "a taking away") is a procedure in which whole blood is removed from the body and passed through an apparatus that separates out one (or more) particular blood constituent. It then returns the remainder of the constituents to the individual's circulation. Through the

use of sophisticated automation, an apheresis procedure can be performed on either a blood donor or a patient.¹ Therapeutic apheresis is the treatment of diseases through removal or extracorporeal manipulation of blood components or specific blood substances. It is distinct from blood component collection by apheresis. The goal of therapeutic apheresis is to remove a pathologic element from blood or to modulate cellular function by

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manipulation such as through extracorporeal photopheresis with or without replacement of the removed element.²

Aims and objectives

In this study we observed the complications after the procedure within 24 hours with respect to patients' demographic profile and procedural variations.

METHODS

This is a one-year (01 September 2020 to 31 August 2021) prospective observational study conducted by Department of Transfusion Medicine in collaboration with Medicine Department, King George' Medical University, Lucknow India. This included all the patients, who required TPE, as a part of their management. For inclusion criteria plasma exchange is done on the request of the patient's physician. who fulfilled criteria for TPE as per the guidelines laid down by Directorate General Health Services (DGHS), Ministry of Health and Family Welfare, Government of India and Drugs and Cosmetics Act, 2020 were included in the study. Exclusion criteria included, patients who was not given inform consent for TPE.

Sample size at 80% power

Sample size is calculated on the basis of proportion of complications after the procedure and changes during the follow up using the formula, where p_1 =0.42 (42%) proportion of complications after the procedure, p_2 = p_1 under null hypothesis, e=0.4, the proportion ratio considered to be clinically significant, type I error, α =5%, and type II error β =20% for setting power of study 80%.

$$n = \frac{(z_{\alpha} + z_{\beta})^{2}}{[\ln(1 - e)]^{2}} \left[\frac{1 - p_{1}}{p_{1}} + \frac{1 - p_{2}}{p_{2}} \right]$$

The sample size is calculated to be n=60.

Ethical clearance

The Institutional ethical committee, King George's Medical University, Lucknow approved my study protocol and procedures of informed consent before the formal survey ref. code: III PGTSC- A Thesis/P21.

Methodology

Therapeutic plasma exchange procedures were performed TPE will be performed on COM. TEC, Fresenius Kabi, Germany®, by using TPE kit, it is a closed system, TPE Fresenius Kabi, Germany® and anticoagulant ACD Fresenius Kabi, Germany®. Normally the range of anticoagulant ACD ratio, will be use during the TPE cycle is 1:8 to 1:12. The range of the blood flow, will use during the TPE procedure is 30 to 50 ml/min.⁴ We observed the patient very carefully, recorded all the complications if it

will be manifested after the procedure within 24 hour the procedure.

Patient's vitals, and blood sample for hematological and renal profile taken within 24 hours after the procedure and properly examine the patient if any complications are found or complained after the procedure within 24 hours and managed appropriately.^{5,6}

RESULTS

In our study total 60 cases and total 150 TPE cycles performed on those who required TPE, as a part of their management. The mean age of total patients was 31.95±11.66. The most prevalent age group was 30-49 years with maximum number of patients [78 (52%)] followed by 10-29 years [66 (44%)] and so on. Further, female dominance was observed [78 (52%)] over males [72 (48%)]. Majority of enrolled patients reported to have BMI>30 [126 (84%)], followed by 25.00-29.99 [22 (14.67%)].

We observed complications within 24 hours after the procedure, out of 150 total TPE cycle, 100 (66.67%) patients reported with no complications. However only [12 (8%)] patients reported complications like abdominal discomfort, followed by cough, hypothermia and mild bipedal edema [08 (5.33%)].

Table 1: Tabular presentation of the BMI distribution based on the complication after 24 hours of procedure.

Complication after 24	BMI		P value
hours of procedure	Mean	SD	1 value
Yes			
Abdominal discomfort	31.47	4.47	
Bipedal edema	30.39	3.90	
Cough	34.27	3.97	
Hypothermia	30.39	3.90	
Infection at phlebotomy	36.34	5.09	t=6.728
site	20.20	2.00	p<0.0001
Internal bleeding	30.39	3.90	
Mild bipedal edema	32.13	3.42	
Vomiting	34.27	3.97	
Death	33.93	5.69	
Total complication	32.22	4.53	
No complication	35.89	4.91	
Total	34.67	5.09	

In this study overall, 59 (75.64%) females were observed without complications however 19 (100%) were observed with complications. Similarly, 41 (56.94%) males were observed without complications and 31 (100%) males were observed with complications. Maximum mean age (36±4) was observed for cough and vomiting both, followed by mean age (33.15±12.70) for no complications. Maximum mean BMI was observed for infection at phlebotomy site (36.34±5.09), followed by no

complications (35.89±4.91) (Table 1). While observing the vital comparison among pre and within 24 hours after procedural variations we have found that highest hemoglobin (Hb), haematocrit (Hct) % and S. calcium was observed pre-procedure. However, highest platelet count, APTT, S. urea and S. creatinine, was observed post 24 hours of the procedure. Similarly considering vitals of the patients, maximum SBP, RR and SpO₂ was observed pre-procedure. However, maximum pulse rate and DBP was observed 24 hours after the procedure.

Table 2: Tabular presentation of the mean variation of S. calcium based on the complication after 24 hours of procedure.

Complication after 24	S. calcium		D 1
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	-0.10	0.32	
Bipedal edema	-0.08	0.04	
Cough	0.62	1.12	
Hypothermia	-0.16	0.90	
Infection at phlebotomy site	2.62	0.00	t=2.461 p=0.0144
Internal bleeding	0.00	0.00	
Mild bipedal edema	-0.56	0.56	
Vomiting	1.59	0.00	
Death	1.21	0.28	
Total complication	0.22	0.99	
No complication	-0.11	1.31	
Total	0.00	1.22	

Table 3: Tabular presentation of the mean variation of S. LDH based on the complication after 24 hours of procedure.

Complication after 24	S. LDH		D 1
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	214.57	237.68	
Bipedal edema	20.50	4.50	
Cough	-35.43	122.07	
Hypothermia	-41.25	124.26	
Infection at	-	0.00	t=4.381
phlebotomy site	244.00	0.00	p<0.0001
Internal bleeding	0.00	0.00	
Mild bipedal edema	497.00	626.09	
Vomiting	191.00	0.00	
Death	161.00	168.00	
Total complication	131.15	350.97	
No complication	-14.08	204.18	
Total	34.33	271.18	

We observed maximum mean variation of hemoglobin was observed for vomiting (2.28 ± 0.00) , followed by internal bleeding (0.80 ± 00) and maximum mean variation of Hct% was observed for internal bleeding (6.00 ± 0.00) , followed by death (1.00 ± 5.20) . Maximum mean variation

of S. calcium was observed for infection at phlebotomy site (2.62 ± 0.00) , followed by vomiting (1.59 ± 00) (Table 2). Maximum mean variation of platelet count was observed for infection at phlebotomy site (1.00 ± 0.00) , followed by cough (0.23 ± 0.67) .

In this study we observed maximum mean variation of S. LDH was observed for mild bipedal edema (497±626.09), followed by abdominal discomfort (214.57±237.68) (Table 3). Maximum mean variation of APTT was observed for cough (22.05±0.34), followed by vomiting (22.02±0.00) (Table 4) and maximum mean variation of PT was observed for hypothermia (13.16±10.47), followed by internal bleeding (12.14±0.00).

Table 4: Tabular presentation of the mean variation of APTT based on the complication after 24 hours of procedure.

Complication after 24	aPTT		Dyolyo
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	0.68	16.02	
Bipedal edema	14.16	0.14	
Cough	22.05	0.34	
Hypothermia	-8.15	4.73	
Infection at phlebotomy site	0.30	0.00	t=5.482 p<0.0001
Internal bleeding	6.50	0.00	
Mild bipedal edema	1.73	13.13	
Vomiting	22.02	0.00	
Death	-3.87	2.73	
Total complication	4.64	14.11	
No complication	18.36	27.21	
Total	13.78	24.53	

Table 5: Tabular presentation of the mean variation of S. urea based on the complication after 24 hours of procedure.

Complication after 24	S. urea		Dwolno
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	-8.24	21.92	
Bipedal edema	6.70	31.30	
Cough	-2.06	1.81	
Hypothermia	-4.60	5.40	
Infection at	-47.20	0.00	t=3.148
phlebotomy site	-47.20	0.00	p=0.0018
Internal bleeding	0.00	0.00	p=0.0016
Mild bipedal edema	-7.56	8.44	
Vomiting	-	0.00	
D 41.	117.34	22.16	
Death	16.85	22.16	
Total complication	-8.95	29.41	
No complication	3.17	36.85	
Total	-0.87	35.02	

We observed maximum mean variation of S. urea was observed for bipedal edema (6.70 ± 31.30), followed by death (16.85 ± 22.16) (Table 5) and maximum mean variation of S. creatinine was observed for abdominal discomfort (0.23 ± 1.54), followed by vomiting (0.21 ± 0.00) and so on, along with statistically significant difference among them (p=0.0003) (Table 6).

Table 6: Tabular presentation of the mean variation of S. creatinine based on the complication after 24 hours of procedure.

Complication after 24	S. creatinine		Dwalna
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	0.23	1.54	
Bipedal edema	0.09	0.01	
Cough	-0.02	0.42	
Hypothermia	-29.37	50.43	
Infection at phlebotomy site	-0.22	0.00	t=3.700 p=0.0003
Internal bleeding	0.00	0.00	p=0.0003
Mild bipedal edema	0.17	0.37	
Vomiting	0.21	0.00	
Death	-58.00	57.60	
Total complication	-9.26	31.53	
No complication	0.27	1.02	
Total	-2.90	18.77	

We observed mean variation of the pulse, based on the complication within 24 hours after the procedure. Maximum mean variation of pulse was observed for vomiting (5.00 ± 0.00) , followed by bipedal edema (2.00 ± 2.00) (Table 7). Maximum mean variation of SBP was observed for cough (7.00 ± 5.20) , followed by bipedal edema (5 ± 00) . While with maximum mean variation of DBP was observed for bipedal edema (5 ± 5) (Table 8).

Table 7: Tabular presentation of the mean variation of pulse rate based on the complication after 24 hours of procedure.

Complication after 24	Pulse		D l
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	-9.83	6.89	
Bipedal edema	2.00	2.00	
Cough	-3.75	6.50	
Hypothermia	0.00	2.83	
Infection at phlebotomy site	0.00	0.00	t=2.526 p=0.0121
Internal bleeding	0.00	0.00	
Mild bipedal edema	-3.00	3.32	
Vomiting	5.00	0.00	
Death	0.00	0.00	
Total complication	-3.08	6.34	
No complication	-1.27	6.07	
Total	-1.87	6.22	-

Table 8: Tabular presentation of the mean variation of DBP based on the complication after 24 hours of procedure.

Complication after 24	DBP		Dyalua
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	-1.67	8.98	
Bipedal edema	5.00	5.00	
Cough	-2.50	8.29	
Hypothermia	-2.50	4.33	
Infection at	0.00	0.00	t=4.309
phlebotomy site	0.00	0.00	p<0.0001
Internal bleeding	0.00	0.00	
Mild bipedal edema	-11.50	7.53	
Vomiting	-8.00	0.00	
Death	0.00	0.00	
Total complication	-2.96	8.00	
No complication	0.66	6.47	
Total	-0.55	7.22	

We observed maximum mean variation of RR was observed for vomiting (6.00 ± 0.00) , followed by mild bipedal edema (2.00 ± 1.41) . Maximum mean variation of SpO₂ was observed for death (1 ± 1) (Table 9).

Table 9: Tabular presentation of the mean variation of SpO₂ based on the complication after 24 hours of procedure.

Complication after 24	SpO ₂		Duolus
hours of procedure	Mean	SD	P value
Yes			
Abdominal discomfort	-2.50	5.80	
Bipedal edema	0.00	2.00	
Cough	-0.50	1.66	
Hypothermia	0.50	0.87	
Infection at phlebotomy site	0.00	0.00	t=2.135 p=0.0336
Internal bleeding	0.00	0.00	
Mild bipedal edema	0.50	1.66	
Vomiting	0.00	0.00	
Death	1.00	1.00	
Total complication	-0.44	3.31	
No complication	0.48	4.11	
Total	0.17	3.89	

In this study we observed complications based on the number of cycles. Out of 150 total patients, maximum complications were observed in 1st cycle (18), followed by 2nd (14) and so on. This emphasizes the decreasing trend of the complications with the increase in number of cycles. Similarly, maximum patients with no complications were observed during 1st cycle (43), followed by 2nd cycle (19) and so on. This emphasizes the increasing trend of the complications with the reduction in patient count having no complications as the number of cycle increases.

We observed that during procedure negative correlation was observed among complication versus all parameters except positive for S. LDH (r=0.1542), APTT (r=0.5521), PT (r=0.1732), S. urea (r=0.2182), and S. creatinine

(r=0.2428). However, the significant association was observed only for complication versus APTT, PT, S. urea, S. creatinine, pulse, SBP, SpO₂ and BMI (Table 10).

Table 10: Tabular presentation of the correlational analysis 24 hours after the procedure among complications and other parameters.

Complication after 24 hours of procedure	Correlation analysis (after the procedure)			
versus	Spearman r	95% confidence interval	P value	
Hb(g/dl)	-0.06273	-0.2253 to 0.1033	0.4457	
Hct (%)	-0.01242	-0.1770 to 0.1528	0.8801	
S. calcium (mg/dl)	-0.1235	-0.2826 to 0.04229	0.1322	
Platelets count (lac cell/mm³)	-0.05588	-0.2188 to 0.1101	0.497	
S. LDH (unit/l)	0.1542	-0.01102 to 0.3112	0.0596	
APTT (sec.)	0.5521	0.4259 to 0.6572	< 0.0001	
PT (sec.)	0.1732	0.008482 to 0.3287	0.0341	
S. urea (mg/dl)	0.2182	0.05529 to 0.3698	0.0073	
S. creatinine (mg/dl)	0.2428	0.08109 to 0.3920	0.0028	
Pulse (bpm)	-0.5649	-0.6676 to -0.4411	< 0.0001	
SBP (mmHg)	-0.1784	-0.3335 to -0.01390	0.0289	
DBP (mmHg)	-0.02529	-0.1894 to 0.1402	0.7587	
RR (breath per min)	-0.1483	-0.3058 to 0.01698	0.07	
SpO ₂ (%)	-0.2299	-0.3804 to -0.06758	0.0046	
BMI (kg/m²)	-0.3298	-0.4692 to -0.1743	< 0.0001	

DISCUSSION

TPE is the procedure in which a large volume of plasma is removed from a patient. The volume removed is such that if it were not replaced, significant hypovolemia resulting in vasomotor collapse would occur. As a result, the removed plasma Must be replaced with some form of replacement fluid.⁷

According to Tabibi et al stated that, ICU patients who received TPE for a range of indications found the following list as the most frequent adverse side effects: decreased arterial blood pressure (8.4% of procedures), arrhythmias (3.5% of procedures), par-esthesia (1.1% of procedures), and cold sensation with transient increases in body temperature (1.1% of procedures).8 Severe and lifethreatening symptoms such as shock, decrease in blood pressure requiring vasopressors, persistent arrhythmia, and hemolysis developed in 2.16% of all procedures performed in ICU patients. But not clearly mentioned that these complications found after the procedure within a 24 hour or not. While in our study we were observed complications within 24 hours after the procedure. Out of 150 total TPE cycles, in 100 (66.67%) TPE cycles reported with no complications. While [12 (8%)] TPE cycles reported to have abdominal discomfort, followed by cough, hypothermia and mild bipedal edema [08 (5.33%)] and so on. Further overall, statistically significant (p=0.0034) difference was observed among both the groups patients having complications and those who don't have.

According to Henriksson et al study, comparison between genders revealed that women experienced more mild

(p=0.03, RR 1.57, CI 1.04-2.38) and moderate (p<0.001, RR 2.0, CI 1.51–2.69) AEs than men when neither albumin nor plasma was used during the apheresis.9 Women experienced more moderate AEs than men when albumin was used as replacement (p<0.001, RR 1.21, CI 1.25-1.83), but not when used in combination with plasma or when plasma was the only option. I had not found any searched article related to after the procedure within 24 hours. In this study, the gender distribution based on the complication within 24 hours after the procedure. Overall, 59 (75.64%) females were observed without complications however 19 (100%) were observed with complications. Similarly, 41 (56.94%) males were observed without complications and 31 (100%) males were observed with complications, along with statistically significant difference among them (p=0.0152).

According to Ghosh et al study, the incidence of complications in the 6~15-year group was higher than that in the $0\sim3$ year and $3\sim6$ year groups, and the incidence of complications in the 30~60 kg group was still higher than that in the $0\sim10$ kg group and $10\sim30$ kg groups. 10 Older age group appears higher complications but not clearly said that about duration. In our study, the age distribution based on the complication 24 hour after the procedure. Maximum mean age (36±4) was observed for cough and vomiting both, followed by mean age (33.15±12.70) for no complications and so on, along with statistically significant difference among them (p=0.0010). In our study the observed mean BMI of total enrolled patients based on the complication 24 hours after the procedure. Maximum mean BMI was observed for Infection at phlebotomy site (36.34±5.09), followed by no

complications (35.89 \pm 4.91) and so on, along with statistically significant difference among them (p<0.0001) (Table 1).

In our study we were observed, the vital comparison among pre and 24 hours after procedural variations we have found that highest Hb, Hct% and S. calcium was observed pre-procedure. However, highest platelet count, aPTT, S. urea and S. creatinine, was observed post 24 hours of the procedure. Similarly considering vitals of the patients, maximum SBP, RR and SpO₂ was observed pre-procedure. However, maximum pulse rate and DBP was observed 24 hrs after the procedure. Further, insignificant difference was observed for all except for PT (p<0.0001) and pulse rate (p=0.0404).

According to Mokrzycki et al study, patients in the lowest Hb and Hct<28.5 had a statistically significantly higher complication rate, with a higher percentage of treatments containing a complication, than patients in the highest two Hct range. 11 The individual complications of fever during treatment, tachycardia, nausea, and severe hypotension were statistically more common in patients with Hct values in the lowest range. Not clearly mentioned duration. In our study, the mean variation of the hemoglobin, based on the complication 24 hours after the procedure. Maximum mean variation of hemoglobin was observed for vomiting (2.28 ± 0.00) , followed by internal bleeding (0.80 ± 00) and so on, along with statistically insignificant difference among them. In our study we were observed the mean variation of the Hct%, based on the complication 24 hours after the procedure. Maximum mean variation of Hct% was observed for internal bleeding (6.00±0.00), followed by death (1.00±5.20) and so on, along with statistically insignificant difference among them.

According to Calca et al study, a total of 46 (45.5%) complications occurred in the 101 TPE sessions. On average, there were 0.46 complications per procedure and 2.1 per patient (range: 1–4) during all TPE sessions. The most frequent complications were transient hypotension (6.9% of procedures) and hypocalcemia (4.9%) but not explain duration. In our study, the mean variation of the S. calcium, based on the complication 24 hours after the procedure. Maximum mean variation of S. calcium was observed for Infection at phlebotomy site (2.62±0.00), followed by vomiting (1.59±00) and so on, along with statistically insignificant difference among them (Table 2).

According to Perdue et al study, comparing the first procedure recorded for each patient, there was a significant difference among instrument types (p<0.001); platelet loss was greater with the Fresenius AS 104 (17.5%, N=21) than with the COBE spectra (1.6%, N=26) or the Haemonetics LN9000 (2.6%, N=24). In our study, the mean variation of the platelet count, based on the complication 24 hours after the procedure. Maximum mean variation of platelet count was observed for infection at phlebotomy site (1.00±0.00), followed by cough (0.23±0.67) and so on,

along with statistically insignificant difference among them.

In this study, the mean variation of the S. LDH, based on the complication within 24 hours after the procedure. Maximum mean variation of S. LDH was observed for mild bipedal edema (497 ± 626.09), followed by abdominal discomfort (214.57 ± 237.68) and so on, along with statistically significant difference among them (p<0.0001) (Table 3). The mean variation of the aPTT, based on the complication within 24 hours after the procedure. Maximum mean variation of aPTT was observed for cough (22.05 ± 0.34), followed by vomiting (22.02 ± 0.00) and so on, along with statistically significant difference among them (p<0.0001) (Table 4).

In our study, the mean variation of the PT, based on the complication 24 hours after the procedure. Maximum mean variation of PT was observed for hypothermia (13.16±10.47), followed by internal bleeding (12.14±0.00) and so on, along with statistically insignificant difference among them. Mean variation of the S. urea, based on the complication 24 hours after the procedure. Maximum mean variation of S. urea was observed for bipedal edema (6.70±31.30), followed by death (16.85±22.16) and so on, along with statistically significant difference among them (p=0.0018) (Table 5).

In our study, the mean variation of the S. creatinine, based on the complication 24 hours after the procedure. Maximum mean variation of S. creatinine was observed for abdominal discomfort (0.23 ± 1.54) , followed by vomiting (0.21 ± 0.00) and so on, along with statistically significant difference among them (p=0.0003) (Table 6).

In our study, the mean variation of the pulse, based on the complication 24 hours after the procedure. Maximum mean variation of pulse was observed for vomiting (5.00 ± 0.00) , followed by Bipedal edema (2.00 ± 2.00) and so on, along with statistically significant difference among them (p=0.0121) (Table 7). Mean variation of the SBP, based on the complication 24 hours after the procedure. Maximum mean variation of SBP was observed for cough (7.00 ± 5.20) , followed by bipedal edema (5 ± 00) and so on, along with statistically insignificant difference among them.

In our study, the mean variation of the DBP, based on the complication 24 hours after the procedure. Maximum mean variation of DBP was observed for bipedal edema (5 ± 5) , along with statistically significant difference among them (p<0.0001) (Table 8).

In our study, the mean variation of the RR, based on the complication 24 hours after the procedure. Maximum mean variation of RR was observed for vomiting (6.00 ± 0.00) , followed by mild bipedal edema (2.00 ± 1.41) , along with statistically insignificant difference among them.

In our study, the mean variation of the SpO_2 , based on the complication 24 hours after the procedure. Maximum mean variation of SpO_2 was observed for death (1±1), along with statistically significant difference among them (p=0.0336) (Table 9).

In our study, the observed complications based on the number of cycles. Out of 150 total patients, maximum complications were observed in 1st cycle (18), followed by 2nd (14) and so on. This emphasizes the decreasing trend of the complications with the increase in number of cycles. Similarly, maximum patients with no complications were observed during 1st cycle (43), followed by 2nd cycle (19) and so on. This emphasizes the increasing trend of the complications with the reduction in patient count having no complications as the number of cycle increases.

In our study, the correlational analysis 24 hours after the procedure among complications and other parameters. We have observed that during procedure negative correlation was observed among complication versus all parameters except positive for S. LDH (r=0.1542), APTT (r=0.5521), PT (r=0.1732), S. urea (r=0.2182), and S. creatinine (r=0.2428). However, the significant association was observed only for complication versus aPTT, PT, S. urea, S. creatinine, pulse, SBP, SpO₂ and BMI (Table 10).

CONCLUSION

Complication within 24 hours after the procedure was abdominal discomfort mainly in males with a correlation with BMI. The correlational analysis within 24 hours after the procedure among complications and other parameters. We have observed that negative correlation was observed among complication versus all parameters except positive for S. LDH (r=0.1542), aPTT (r=0.5521), PT (r=0.1732), S. urea (r=0.2182), and S. creatinine (r=0.2428). However, the significant association was observed only for complication versus APTT, PT, S. urea, S. creatinine, pulse, SBP, SpO₂ and BMI. This emphasizes the decreasing trend of the complications with the increase in number of cycles.

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