EFFECT OF 6 % HYDROXY ETHYL STARCH (130/0.4) ON RENAL FUNCTION, COAGULATION AND MORTALITY IN PATIENTS UNDERGOING HEMIPELVECTOMY SURGERY INVOLVING MAJOR HAEMORRHAGE- A RETROSPECTIVE STUDY

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BACKGROUND

The use of 6% hydroxyethyl starch 130/0.4 (HES) in patients with severe sepsis is associated with increased acute kidney injury (AKI), coagulopathy and mortality. Patients receiving HES during major surgery may be different from patients with severe sepsis, and fluid resuscitation with HES may not be associated with adverse long-term outcomes in these patients.

AIMS AND OBJECTIVES

We aimed to compare the occurrence of postoperative AKI, coagulopathy and mortality in patients who received HES with those who did not receive HES for major haemorrhage in surgery for pelvic bone tumours.

PRIMARY OBJECTIVE

Composite end-point of Number of patients developing:-

- 1) Acute Kidney Injury (RIFLE Stage Injury or Failure), where
i) Injury: highest recorded S. creatinine 2.0 times baseline S. creatinine
ii) Failure: Increased S. creatinine $\times 3$ or creatinine ≥ 4 mg/dl
- 2) OR coagulopathy after surgery (platelet count $< 80,000/\text{cu mm}$ or INR > 1.5 or APTT > 1.5 times pre-operative value)
- 3) OR death prior to hospital discharge.

SECONDARY OBJECTIVE

- 1) Number of patients developing AKI and coagulopathy during the hospital stay.
- 2) Highest increase in S. Creatinine from the preoperative value during the hospital stay.
- 3) Mortality during the hospital stay and at 90 days after surgery.
- 4) Number of patients with AKI at 90 days after surgery.

METHODOLOGY

- 1) After Ethics Committee approval, records of 102 patients between January 2011 and June 2016 were reviewed.
- 2) Patients were classified as those who received HES during surgery and those who did not.
- 3) Preoperative values of Serum creatinine, Platelet count, INR and APTT were compared to the worst post-operative values during the hospital stay.
- 4) Values of Serum creatinine and survival status at 90 days after surgery were also recorded.
- 5) Data was analysed using Chi square test / Fishers exact test, independent “t” test and Multivariate binary logistic regression analysis. P-value < 0.05 was considered statistically significant

RESULTS

TABLE-1 PATIENT DEMOGRAPHICS AND BASELINE PARAMETERS

Baseline parameters (Preoperative values)	GROUP HES (n= 42)		GROUP NON HES (n=60)		p
	MEAN	SD	MEAN	SD	
Age (years)	37.88	15.12	34.52	15.82	0.285
Weight (in kg)	55.5 (n=32)	14.671	57.29 (n=51)	17.61	0.632
Serum Urea (mg/dl)	20.69	7.40	20.18	6.46	0.714
Serum Creatinine (mg/Dl)	0.85	0.15	0.84	0.19	0.78
Hb (gm/Dl)	11.61	1.86	12.53	1.89	0.018
platelet counts ($\times 10^9/\text{L}$)	270.57	111.83	296.85	97.63	0.211
INR	1.11	0.107	1.06	0.134	0.054
APTT	28.31	3.91	29.36	3.34	0.151
PT	14.35	1.19	14.52	1.47	0.533
Duration Of Anaesthesia (min)	449	147	389	134	0.036

FIGURE-1 COMPOSITE END POINT

Composite End Point of Number of Patients Developing Acute Kidney Injury OR Coagulopathy after Surgery, OR Death Prior To Hospital Discharge was similar in both group of patients (p – 0.934).

*37 patients in HES group (n=42) and 46 patients in the NON HES (n=60) group were analysed for composite end point.

** Patients in the HES group received a median dose of 1000 ml 6% HES & a mean dose of 1220.24 ml (S.D of 698.872)

TABLE 2 Shows the similar incidence of AKI, coagulopathy and death during the hospital stay and at 90 days after surgery in both groups.

SECONDARY END POINTS	HES GROUP (n=42)	NON HES GROUP (n=60)	p
No. Of patients with AKI during hospital stay	1 (2.9%) (n=35)	2(4.34%) (n=55)	0.727
No. Of patients with coagulopathy during hospital stay	23 (59%) (n=39)	28 (50.9%) (n=55)	0.439
Mortality during hospital stay	1 (2.4%)	1 (1.7%)	0.798
MORTALITY at 90 days after surgery(including during hospital stay)	2 (5.7%) (n=35)	1 (2%) (n=51)	0.351
No. of patients with AKI at 90 days after surgery	0 (n=17)	0 (n= 30)	
Mean ratio of the Highest value of S.creatinine in the post-operative period to the pre-operative S. creatinine	1.044 (n=35)	1.11 (n=46)	0.604

DISCUSSION

In our study, administration of median dose of 1000ml of 6%HES (130/0.4)was not significantly associated with a postoperative deterioration in renal function or coagulopathy or mortality both during the hospital stay and at 90 days after surgery.

LIMITATION

- 1) Retrospective study:- a) Limitation on availability of a relevant data and the missing data could not be accounted for.
- 2) Unaccountability for the type of postoperative fluid administration (colloid/crystalloid) which may have influenced the outcome.

CONCLUSION

We believe that data from this study could be used to justify undertaking a randomised controlled trial of 6% HES 130/0.4 for fluid resuscitation during major surgical haemorrhage to determine its safety and effectiveness.

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