Original Research Article

Retrospective analysis of ureteroscopic management of renal calculus disease in patients with coagulopathy secondary to chronic liver disease – A single centre experience

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Abstract

Objective: Hepatic-coagulopathy is commonly seen in about 70-80% of the patients with chronic liver disease (CLD) and it differs remarkably from other coagulopathies. Urological interventions pose a unique challenge in patients with coagulopathy secondary to CLD. The purpose of this study was to evaluated the safety of ureteroscopic management of renal and ureteric calculi in CLD patients with coagulopathy. **Material and Methods:**We retrospectively analysed outcome of ureteroscopic procedure (rigid and flexible both) performed in patients with CLD (CLD group, n=13) and in patients without CLD (Non-CLD group, n=39). Similar perioperative protocols were used in both the groups. Prothrombin time (PT) and International Normalized Ratio (INR) were used to rule out coagulopathy in both the groups, however, in CLD group Thromboelastogram (TEG) was done additionally. In the perioperative period, correction of coagulopathy in CLD group was guided by TEG results rather than PT/INR results. Postoperative outcomes of both the groups were compared statistically.**Results**Both the groups had comparable demographic profile, preoperative haemoglobin levels, platelet counts and stone size. In the CLD group, based on the TEG results, one patient received preoperative platelet transfusion and three patients received preoperative fresh frozen plasma (FFP) transfusion. Post-operative complication rates (15.4% Vs 10.2%, p=0.55), hospital stay (1.46 ± 0.88 days Vs 1.27 ± 0.67 days, p=0.41) and stone free rates (78.4% vs 81.1%, p = 0.77) were comparable in both CLD and Non-CLD groups respectively. Incidence of postoperative haematuria requiring blood transfusion was significantly higher in CLD group (15.4% Vs 0, p=0.01). **Conclusion:**Ureteroscopic management of renal and ureteric calculi is a safe procedure in CLD patients and its stone free rates are comparable to non CLD patients. However, the risk of bleeding in these patients is significantly higher compared to non-CLD subjects. Perioperative transfusion in CLD patients should be guided by TEG.

Keywords: ureteroscopy, chronic liver disease, coagulopathy, thromboelastogram, renal calculi

Introduction

Patients with chronic or acute liver disease are conventionally presumed to have higher bleeding tendencies secondary to coagulopathy.Due to risk of bleeding, Percutaneous nephrolithotomy, laparoscopic procedure and Shock wave lithotripsy are contraind-icated in these patients with uncorrected coagulopathy. Ureteroscopic removal of ureteric and renal calculi is a preferred option in these patients, but it is also associated with perceived concerns of intraoperative poor vision (due to bleeding), haematuria requiring blood transfusion, increased risk of infections and low stone free rates.Though, ureteroscopy in normal patients has shown to achieve a stone free rate of around 81%, 86%, and 94% for upper, mid and lower ureteric calculi respectively, some authors have shown significantly lower stone free rates in patients with coagulopathy [1,2]. However, most of these studies were done in patients with coagulopathy secondary to anticoagulants. It is interesting to note here that, coagulopathy secondary to chronic liver disease (CLD) behaves differently from coagulopathy secondary to anticoagulation. Patient with CLD are in a state of compensatory hypercoagulable state[3] and rebalanced haemostasis[4]. Thus, the same yardstick cannot be used for management of coagulopathies due to different causes.Classification of CLD is done using either Child-Pugh Criteria or Preoperative Model for end stage liver disease (MELD) scores. Higher the scores, higher is the chance of perioperative morbidity and mortality[5-7]. However, these scores are developed primarily by evaluating the outcome of open surgery in CLD patients, and not for endoscopic procedures. Through this retrospective study we have tried to investigate safety and outcome ofureteroscopic procedures done for renal or ureteric calculi in patients of chronic liver disease (CLD).

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Materials and methods

This study was conducted at a tertiary care institute, primarily catering patients of liver diseases. We retrospectively analysed all the thirteen CLD patients, who underwent ureteroscopic procedure for renal or ureteric calculi at our institute, between January 2016 to January 2017. To compare the outcomes with a control group (non

CLD group), patients were selected retrospectively in the non CLD group in a ratio of 1:3 after age, sex and stone size matching by an independent statistician. Finally, fifty-two patients were included in the study and were divided into two groups. Patients with chronic liver disease were categorized into CLD group (n=13), who underwent five Ureterorenoscopy (URS) and eight Retrograde Intrarenal Surgery (RIRS) procedures, and patients without liver disease were categorized into Non-CLD group (n=39), who underwent 15 URS and 24 RIRS. Patients with CLD were admitted one day prior to the procedure and patients without CLD were admitted in the morning of the day of surgery.All the patients underwent preoperative complete blood count, renal function test, urine cultures, coagulogram (PT/INR) and CT scan. In addition, patients with CLD were preoperatively evaluated by a Hepatologist and they underwent a liver function test (LFT) and throboelasogram (TEG). Based on LFT, patients with CLD were classified according to Child-Pugh classification into A, B and C groups. Preoperative Model for end stage liver disease (MELD) scores and 30-days postoperative mortality risk was calculated using online available tools (Mayo Clinic post-operative mortality in patient with cirrhosis)[8]. In CLD patients, perioperative transfusion of blood products (to correct the coagulopathy, if required) was guided by TEG result, rather than PT, INR or platelet count. Ureteroscopic procedures were done under general anaesthesia. Antibiotic protocol was similar in both the groups. Holmium LASER was used for stone fragmentation in both the groups. Double J (DJ) stent was placed in all the patients after the procedure. Similar post-operative protocol was followed in both the groups. DJ stent was removed 2 weeks after URS and 4 weeks after RIRS, irrespective of the patient group. X ray KUB and sterile urine cultures were obtained prior to DJ stent removal.The outcome of these procedures in terms of stone free rate, haematuria requiring blood transfusion, post-operative hospital stay and complication rates was analysed retrospectively for both the groups. Clavien-Dindo classification was used to grade the complication[9]. Stone clearance was defined as absence of any residual fragments or stone fragments less than 2mm at 1-month follow-up. Significant intraoperative and postoperative haematuria was defined as more than 1 g drop in haemoglobin levels on the first post-operative day.

Table 1:Pre-operative details of patients in both the groups

	CLD Group (n=13)		Non- CLD Group (n=39)		p Value
	Mean ± SD	Range	mean ± SD	Range	
Age (years)	52.38±11.99	34 – 74	47.56± 12.53	22 – 68	0.23
Pre OperativeHaemoglobin (gm/dl)	9.38 ±2.029	7.2 – 13.3	12.38± 1.85	8.8 – 15.8	0.74
Pre Operative INR	1.50± 0.30	1.18 – 2.07	1.05±0.15	0.78 – 1.5	0.001
Pre Operative PT	17.60±3.39	12.7 – 23	11.92±0.95	10.4 – 16	0.001
Pre Operative Platelets (Thousands/dl)	118.31±77.1	31 – 272	208.51±124.30	98 – 864	0.68
Stone Size (mm)	14.52± 6.96	5 -29	12.08± 4.40	6 – 26	0.12

Table 2:Showing pre and postoperative need of Blood and Blood products Transfusion in CLD group Patients

Sr No.	Preoperative Platelet count (per dl)	Preoperative Prothrombin time (PT)	Preoperative International Normalized Ratio (INR)	Preoperative Haemoglobin (gm/dl)	Preoperative Thromboelastogram (TEG)	Preoperative Transfusion	Postoperative Event
1	31,000	18	1.4	9.6	Abnormal	Single SDPC transfused	-
2	3,31,100	17.55	1.44	7.2	Abnormal	FFP Transfused	Developed Haematuria (Hb= 6.2 gm/dl), 2 units Packed RBC transfused Postoperative TEG normal- NO FFP transfused.
3	2,47 ,000	17.10	1.36	11.2	Abnormal	FFP Transfused	-
4	2,72,000	19.2	1.5	13.3	Abnormal	FFP Transfused	-
5	46,300	15.9	1.42	8.3	Normal	-	-
6	3,41,000	12.7	1.70	8.6	Normal	-	-
7	53,800	18.6	1.17	8.4	Normal	-	-
8	4,10,000	16.5	2.07	9.8	Normal	-	-
9	62,000	23	2.02	9.2	Normal	-	Developed Decompensation of CLD with Haematuria (HB =7.9 gm/dl),1 unit Packed RBC Transfused, TEG Abnormal- FFP transfused.
10	88,000	21	1.52	9.3	Normal	-	-
11	79,400	14.2	1.38	8.9	Normal	-	-
12	84,500	22	1.18	10.2	Normal	-	-

13	3,11,000	13	1.34	7.9	Normal	-	-

Table 3:Comparisons of postoperative outcomes of both groups

	CLD Group (n=13)	Non- CLD Group (n=39)	p Value
Post OperativeHaematuria requiring transfusion (%)	2 (15.4%)	0	0.01
Clinically significant residual fragments (%)	3 (23.1%)	5 (12.8%)	0.34
Post Operative Complications (%)	2 (15.4%)	4 (10.02%)	0.55
Post Operative Hospital Stay (days) mean ± SD	1.46 ± 0.88	1.27 ± 0.67	0.41

Results

Preoperative Comparison: There were 10 males and 3 females in CLD group and 30 males and 9 females in non CLD group. Both the groups were comparable in terms of age, preoperative haemoglobin, platelet counts and stone size, whereas preoperative International normalized ratio (INR) and prothrombin time (PT) were significantly higher in CLD group (Table 1).According to Child-Pugh criteria, CLD group had 1 patient in group A, 7 patients in group B and 5 patients in group C. Mean preoperative MELD score of CLD group was 16.31 ±5.9 (range 8 – 27) and mean 30-days post-operative mortality risk in CLD group was 15.7% (range 6.33% – 46.1%).

Need for Preoperative Transfusions:TEG report was abnormal in 4 (30.8%) patients. Based on TEG report, one of the four patients with platelet count of 31 thousand/dl received preoperative single donor platelet concentrate (SDPC) transfusion, whereas other patients with even lower platelet counts were not given platelet transfusion as there TEG report was normal. Similarly, based on their TEG results, three other patients received preoperative fresh frozen plasma (FFP) transfusion, even though their INR reports were within normal range. Whereas, two other patients with INR greater than 2 and normal TEG report were not given any preoperative FFP transfusion. (Table 2)

Postoperative Outcome: Mean operative time in both the groups was statistically similar. On analysing the postoperative outcomes of both the groups, there was no significant difference in postoperative hospital stay and clinically significant residual fragments (CSRF). No change in postoperative INR values was seen in CLD group, whereas a mean fall of 26.46 thousand/dl was seen in platelet counts but it was not statistically significant. A significant fall of 0.45 gm/dl was seen in haemoglobin postoperatively (Table 3).

Overall complication rates were equal in both the groups (15.4% vs 10.02% ,p=0.55). However, Incidence of postoperative haematuria requiring blood transfusion was higher in CLD group (n=2, 15.2%). In CLD group, while one patient developed haematuria requiring blood transfusion (grade II), other patient developed haematuria along with liver decompensation (Grade IV). In Non-CLD group, 2 patients developed urosepsis (Grade II), one patient had forniceal rupture (Grade II) and other patient had ureteric injury while retrieving the broken end of stone retrieval basket during RIRS (Grade II). (Table 3)On analysis of CLD group, no correlation of preoperative haemoglobin, platelet counts, INR and stone size were found with CSRF and postoperative haematuria requiring blood transfusion.

Statistical analysis: The data is expressed as mean ± SD or in frequency. The categorical data was analyzed using Chi-square or Fisher's exact test wherever applicable. The continuous data was analyzed using Student's t-test or Mann Whitney test as appropriate. The predictors of postoperative outcomes like need for blood transfusion, clinically significant residual fragments, postoperative complications and postoperative hospital stay were analyzed using univariate and multivariate logistic regression. The correlation between continuous variables was analyzed using Pearson correlation coefficient. For all the tests, p value < 0.05 was considered significant.

Discussion

Choosing optimal modality for stone clearance in coagulopathy

The optimal management of renal and ureteral calculi in patients with uncontrolled coagulopathy poses a difficult situation to most of the surgeons. Factors such as increased risk of bleeding, poor vision during the procedure (due to bleeding), increased risk of infection, low stone free rates and increased duration of stay are to be considered while choosing the optimal modality for their management. Conventionally, SWL, PCNL and laparoscopic surgery are contraindicated in patients with uncontrolled coagulopathy as they pose an increased risk of bleeding and poor stone clearance rates [10]. Out of the available modalities for stone management, ureteroscopic management of ureteral and renal calculi is relatively considered safe in these patients. Stone clearance rate after ureteroscopic management of ureteral calculi in patients without coagulopathy is considered to be around 81%, 86%, and 94% for upper , mid and lower ureteric calculi respectively, but the outcome of ureteroscopic procedures in patients with uncontrolled coagulopathy is variable in different studies in terms of postoperative bleeding and stone clearance rates[1]. Turna et al., retrospectively analysed 37 patients on anticoagulation therapy who underwent ureterorenoscopy for renal stones and matched controls were compared with them[10]. They found no significant difference in the stone free rates in both the groups (78.4% vs 81.1% respectively, p = 0.7725). Klingler HC et al [11]. in their retrospective analysis of 7 patients with coagulopathy who underwent ureteroscopic management, reported a 100% stone clearance rate with no postoperative complications. In their study of nine patients with coagulopathy, who underwent URS and Holmium Laser lithotripsy, Mohamed et al [2]. reported a lower stone free rate after first URS (69.2% vs 94.1%, p = .04) compared to patients without coagulopathy, however the stone free rates were comparable after second URS in both the groups. In our study, we reported a stone clearance rate of 76.9 % in CLD group and 87.8% in Non CLD group, but it was not clinically significant (p = 0.35). Thus, in our study, ureteroscopic management of renal and ureteric calculi in CLD patients was able to achieve equivocal stone clearance rates compared to non CLD patients. While performing ureteroscopy in CLD patients, we did not encounter intraoperative bleeding or poor vision due to bleeding.

Evaluation of coagulopathy secondary to CLD needs a different approachCLD-associated coagulopathy behaves differently from coagulopathies due to other known causes. Since, most of the studies which evaluated outcome of ureteroscopy in patients with coagulopathy, included coagulopathy secondary to anticoagulation therapy, their results cannot be extrapolated in patients with CLD related coagulopathy. The present study evaluated the outcome of ureteroscopy in patients with coagulopathy secondary to liver disease. Haemostatic defect in CLD is a complex process, involving opposing factors of primary haemostasis, coagulation, and

fibrinolysis. Patients with liver cirrhosis are presumed to be at higher risk of bleeding due to elevated INR (secondary to liver dysfunction) and thrombocytopenia (secondary to portal hypertension and hypersplenism). But contrary to conventional belief, recent studies have shown a compensatory hypercoagulable state and increased platelet adhesion in these patients due to rebalanced haemostasis [3][4]. However, compared to normal individuals this state of rebalanced haemostasis is fragile in liver cirrhosis patients and can be disturbed by factors like infection and renal dysfunction. Thus, it is debated that routine standard laboratory methods for evaluating coagulopathy are not useful in patients with liver dysfunction and it is better assessed by viscoelastic methods for the global assessment of coagulation like thromboelastogram (TEG) or Sonoclot assay. Using five different parameters, a TEG study can evaluate: (1) time between initiation of coagulation cascade to initial formation of fibrin, (2) time between initial formation of fibrin to specific clot firmness (20 mm), (3) rate of fibrin formation and cross linking, (4) maximum clot strength and fibrinolysis 30 minutes after maximum amplitude[12].These parameters provide a guide for pre and post-operative blood product transfusion irrespective of other laboratory parameters like INR, PT and platelet counts. In a study published from our institute, which evaluated and correlated clinical bleeding and the commonly used laboratory tests for haemostasis in CLD patients, it was concluded that there was no correlation of bleeding with prolonged PT/INR, decreased platelet count and adverse clinical outcome[13]. Thus, we want to emphasise that pre-operative evaluation of coagulopathy in CLD patients should be done by TEG and not by the PT/INR or platelet counts alone.

Need for perioperative Transfusions. Based on TEG report, one patient received preoperative single donor platelet concentrate (SDPC) transfusions. His platelet counts were 31 thousand/dl, whereas six other patients with platelet counts lower than 90 thousand/dl (ranging from 46 to 88 thousand /dl) were not given platelet transfusion as their TEG reports were normal. Three patients received preoperative fresh frozen plasma (FFP) transfusion based on TEG report. Their INR reports were within normal range, whereas other two patients with INR greater than 2 but normal TEG report were not given any preoperative FFP transfusion. If not for TEG, these six patients with thrombocytopenia and two patients with abnormal INR, otherwise would have received unnecessary transfusions. Unnecessary transfusions given on the basis of routine tests put patients at risk of circulatory overload and allergic reactions. A recently published study emphasized that prophylactic transfusions of platelets and plasma in critically ill patients, prior to invasive interventions, is just useless, expensive and even harmful [14]. In addition, the time that is wasted in correcting these abnormal laboratory parameters, on occasions, delay the much-needed intervention. Thromboelastometry based transfusions are not only cost-effective, but also optimize the resources and prevent transfusion associated adverse effects. It is still a common practice to order platelet and plasma transfusions and even injectable vitamin K in CLD patients with abnormal coagulation parameters, but the practice needs to be abandoned in favour of thromboelastometry based transfusions. In the present study, two patients received post-operative blood transfusion. First patient had an abnormal preoperative TEG report and low preoperative haemoglobin (7.2gm/dl). Based on these reports, he was transfused one-unit packed RBC and 4 units FFP preoperatively. He developed postoperative haematuria with haemoglobin fall upto 6.2gm/dl for which two units of blood were transfused, however his postoperative TEG report was normal, so no blood products were transfused postoperatively. His haematuria resolved spontaneously within 24 hours. Second patient with a high preoperative INR (2.02), PT (23 sec) and low platelet count (62 thousand/dl), but a normal TEG report developed post-operative liver decompensation and haematuria with a fall in haemoglobin (9.8 to 7.9 gm/dl). Based on his postoperative TEG report, FFP transfusion was given to him. His haematuria resolved with improvement of liver compensation. Thus, the present study emphasizes the role of TEG in evaluation and management of CLD related coagulopathy, rather than relying on standard routine coagulogram parameters (PT/INR).

MELD Score and Mortality Many studies have shown increased incidence of morbidity and mortality in CLD patients with higher Child-Pugh and MELD scores [5-7]. Earlier studies have reported 30% mortality rate in Child class B and 70 – 80% mortality in Child class C patients, undergoing major abdominal surgeries [15,16]. Thus, they practically contraindicated elective surgeries in Child class C patients. In the present study, about 53% CLD patients were Child-Pugh category B and 38% patients were in category C. Based on the MELD score, the mean 30-days post-operative mortality risk in CLD group was 15.7%, ranging from 6.33% – 46.1%. Even with such high number of patients in Child class C and higher mortality prediction score, we had no mortality in our study. This can be understood from the fact that, these prediction scores were mainly derived from the outcome of major open abdominal surgeries and does not fit accurate for ureteroscopic procedures.

ComplicationsApart from bleeding, CLD patients are at higher risk of other complications such as decompensation, infection and sepsis. In CLD group while one patient developed liver decompensation with haematuria and other developed haematuria without liver decompensation, none of the patient developed urosepsis. In Non-CLD group, 2 patients developed urosepsis, one patient had forniceal rupture and other patient had ureteric injury while retrieving the broken end of stone retrieval basket during RIRS. All the patients were managed conservatively. Though, the overall postoperative complication rates were statistically similar in both the groups, CLD group had higher grade of complication according to Clavien-Dindo Classification[9]. CLD patients are always at risk of postoperative hepatic decompensation.

Hospital Stay Patients with CLD were admitted one day prior to surgery, whereas patients in Non CLD group were admitted on the day of surgery. Postoperative hospital stay was statistically significant in both the groups. Postoperative haematuria was the main cause of prolonged hospital stay in CLD group, whereas urosepsis was the main cause in non CLD group.

Conclusion

TEG guided peri-operative transfusions have become standard of care in other specialties and our study now emphasizes its significance in urological procedures, to prevent unnecessary transfusions. Ureteroscopic management of renal and ureteric calculi in these patients gives equivalent outcomes in terms of stone clearance rates, post-operative complications and postoperative hospital stay. However, the risk of bleeding in these patients is significantly higher compared to non-CLD subjects.

LimitationThe main limitation of our study was its small sample size and retrospective nature of the study. We need a further large prospective study to validate our results.

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