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Role of uterine balloon tamponade to avert morbidity and mortality due to post-partum haemorrhage in pregnancy with hepatitis e virus infection: A case series

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Abstract
Aim: To assess the role of condom balloon tamponade in arresting the primary PPH in pregnant women with hepatitis.
Material and methods: This case series included pregnant women with hepatitis e admitted in department of obstetrics and gynecology of a medical college from January 2016 to April 2020. Demographic details, labour findings and feto-maternal outcome was noted and assessed.
Results: During study period 40 women presented with hepatitis e. 20 were included in study group and 20 in control group. Condom balloon tamponade prevented PPH in women with hepatitis e with a success rate of 100% (P value=0.01). It controlled PPH with DIC, severe anaemia and hepatic encephalopathy as depicted by OR<1. Balloon tamponade had averted invasive procedures like pelvic devascularisation, compression sutures and peripartum hysterectomy in these women.
Conclusion: Condom balloon tamponade has a definite role in averting PPH in hepatitis e pregnancy thus improving the maternal and fetal outcome.

Keywords: Condom balloon tamponade, caesarean delivery, hepatitis e, post-partum haemorrhage, uterine atony, uterotonics, vaginal delivery

Introduction
As per the latest WHO estimates, around 20 million of people get Hepatitis E Virus (HEV) infection every year. Out of which 3.3 million become symptomatic and approximately 44000 die [1]. All viral hepatitis including HEV is caused by the corresponding hepatotropic viruses. HEV as well as Hepatitis A are transmitted by feco-oral route and cause acute hepatitis [2]. Due to lack of hand hygiene and clean drinking water supply, India is an endemic area for these viruses [3, 4, 5]. Although HEV can affect people of any age group but when occurs during pregnancy, the outcome can be devastating. In general population the disease runs a self-limiting course with low chances of developing fulminant hepatitis but in pregnant women acute liver failure can occur more frequently. When occurs in third trimester of pregnancy, the mortality rates are reported to be as high as 20-25% [1, 6]. High maternal mortality rate in pregnancy with HEV is owing to complications like hepatic coma, deranged coagulation profile, abruptio placentae and postpartum haemorrhage. Management of PPH in these women poses a challenge especially when many drugs of the first line intervention which is the medical treatment, are contraindicated in acute parenchymal liver disease and the third line intervention of surgical recourse is often not feasible in lieu of existing or potential coagulation abnormalities. That leaves second line interventions like uterine balloon tamponade (UBT) which can play a crucial role in cases not amenable to medical management. Though timely management by first line intervention of PPH remains the cornerstone of treatment [7-10], the use of UBT as prophylaxis or as treatment can go a long way in reducing the blood loss and prevent or treat PPH leading to curtailment of morbidity and mortality associated with it.
UBT involves insertion of a balloon into the uterine cavity followed by its inflation in order to achieve a tamponade effect and stop the bleeding. It is a safe and very effective intervention [11-17]. Out of many variants of available UBTs, the commercially available purpose designed UBT "Bakri balloon®" though it is not a cost-effective option for LMICs (lower middle-income countries). Amongst the low-cost option of UBT, condom balloon tamponade (C-UBT) device is the most widely used with comparable efficacy [18-29].

There are many modifications of C-UBT used particularly in centres with low resources. In our tertiary care centre while dealing with delivery of women with HEV infection, we have started using C-UBT for last five years and observed its significant role in the improvement of maternal outcome whereas previously the outlook remained dismal with PPH and disseminated intravascular coagulation being the main culprit [6]. The present study was done in largest and oldest teaching institute of Chhattisgarh which was also the first teaching hospital to have started using UBT in the state. The objective of the study was to document the role of C-UBT in prevention and treatment of PPH in women with HEV and its effect on maternal outcome.

Material and Methods

Present retrospective observational case series was conducted from January 2016 to April 2020 in the department of Obstetrics & gynaecology in a Government Medical College of Central India. All pregnant women with HEV infection who delivered in our institution from January 2016 to April 2020 (4 years and 4 months) with complete data available were included in the case series. Details regarding demographic data, relevant clinical characteristics, blood investigations and feto-maternal outcome were recorded in a prepared proforma.

The UBT used in the present study were two variants of the C-UBT named CG Balloon and Easy balloon [30, 31]. [Fig 1] These are prepared at the point of care and used in the manner described in these research papers.

All women have undergone active management of third stage of labour (AMTSL).

Soon after delivery of baby and placenta, quick assessment of these women was done and prophylactic insertion of C-UBT was done. In case the women started bleeding significantly after delivery before prophylactic insertion of C-UBT and PPH was diagnosed as bleeding of > 500 mL after vaginal delivery and > 1000 mL in caesarean section, it was managed by uterine massage, bladder drainage and use of uterotonics as the first line intervention in cases of atonic uterus, failing which the C-UBT was inserted. Retained products of conception and genital tract trauma were excluded prior to its insertion. If the bleeding was not controlled in spite of inflation volume of 500 mL of normal saline in the UBT, failure of C-UBT in this negative tamponade test was noted and considered for the third line or urgent surgical intervention. Pelvic devascularization, compression sutures, obstetric hysterectomy were used as a measure to control intractable haemorrhage. In case the bleeding was controlled with C-UBT, the woman was kept under constant observation, catheterised and the C-UBT was removed after 6-24 Hrs. These women constituted the study group.

Women with HEV infection in whom C –UBT was not used either for prophylaxis or treatment after delivery constituted the control group. Amongst the two groups, apart from the use of C-UBT, the treatment did not differ. All the women were jointly managed by department of Obstetrics, Medicine and Anaesthesia. The maternal outcome was compared in terms of incidence of PPH in the two groups as the primary outcome whereas secondary outcomes were the number of transfusions of blood products, surgical intervention for PPH, need of ICU admission maternal morbidity and mortality and duration of hospital stay.

Exclusion Criteria

Women with rupture uterus, hepatitis A, hepatitis B, hepatitis C, gestational thrombocytopenia, acute fatty liver of pregnancy, thrombophilias, known case of coagulation disorder, hemolytic anaemias, hemoglobinopathies and chronic liver diseases were excluded from the study.

Statistical Analysis

The data was entered into Excel 2020 sheet and analysed with SPSS version 20. Results were reported as mean, SD or number percentage. Student's unpaired t test was used for analysis of continuous variables whereas the categorical variables were analysed by Chi square test with p = <0.05 considered as significant. Odds ratio (OR) and corresponding 95% confidence intervals (95% CI) were calculated for categorical data.

Results

During the study period 43341 women were admitted with 30610 deliveries in our department. Of these, 40 women were diagnosed with HEV hepatitis e and fulfilled the inclusion criteria. 20 women were included in study group and 20 in control group. Both groups were statistically comparable in demographic details in terms of age, parity, education, occupation and booking status (table no 1). Being the largest tertiary centre of the state, referrals were also higher in both the groups.

Majority of the women had singleton pregnancies (study group 85% and control group 95%) with spontaneous onset of labour. Vaginal delivery was the most common route in both groups with share of 30% for c-section in control group. The mean gestational age on admission was 32 weeks. Most of the babies delivered were preterm with a mean weight of 1900± 170 gms (table no 2).

Indications of C-UBT in study group was showed in figure 1. Atony of uterus was the cause in 20% of women whereas prophylactically balloon was inserted in 60%.

The success rate of balloon tamponade was 100%. The mean inflation volume was 280±96 mL and mean duration keeping C-UBT in situ was 15.4±2.3 hrs. None of the women had a recurrence of bleeding after removing the C-UBT. Table no 3 depicts the comparison in the maternal outcome of the two groups. When compared to the control group, the odds of having PPH with the use of C-UBT were significantly less with Odds Ratio (OR) of 0.16, 95% CI 0.04-0.68, (p=0.01= highly significant). C-UBT in study group had beneficial effect by controlling uterine bleeding even with DIC, severe anaemia and hepatic encephalopathy as depicted by OR<1. Also, use of balloon tamponade had averted invasive procedures like stepwise pelvic devascularisation, compression sutures and peripartum hysterectomy (OR=0.08 95% CI is 0.004-1.7) resulting in lesser admissions in ICU (OR==0.02, 95% CI is 0.001-0.3, P=0.009 highly significant) and less maternal mortality (OR=0.18, 95% CI is 0.04-0.71, P=0.01 highly significant) compared to control group.

Table no 4 compares the lab parameters, blood products administration, ICU admissions and mean duration of stay in the two groups. The prothrombin time (21.3+3.5) seconds, international normalised ratio (2+0.3), mean serum total bilirubin (12.4+2.5) mg/dl, mean direct bilirubin (8.1+1.9) mg/dl, mean SGOT (548+141.7), mean SGPT (219+62.3), mean total FFP transfusion (11.8+3.1), mean total blood transfusion (3.4+2.1) of control group was higher than study group. PPH in them was managed by compression sutures in 6 women, pelvic devascularisation in 2 and peripartum hysterectomy in 1. Rest all were managed by conservative management in ICU involving blood and FFP transfusion.

Looking at the maternal outcome, results of women in study

group with C-UBT were better with 25% required ventilator, 72% were discharged and 28% maternal mortality. On the other hand, in control group (women without C-UBT) these percentages were 55%, 30% and 70% respectively (fig 2). Also, the mean number of days spent in ICU (1.75+0.80) and total hospital stay (5.3+1.09) were much superior in women of study group against the respective figures of 8.4+0.9 and 8.2+1.6 days (table no 4) in opposite group indicating early recovery with C-UBT.

On studying foetal outcome, NICU admissions and neonatal deaths were 20% and 15% in study group whereas in control group they were 15% and 10% (fig 3). Of 4 neonate of study group admitted in NICU, 3 were discharged whereas in control group out of 3 neonates in NICU only 1 was improved and discharged.

Discussion

Hepatitis E in pregnancy is a nightmare both for the woman and the treating obstetrician. In addition to high maternal mortality and morbidity, HEV also causes adverse foetal outcome like miscarriages, stillbirths, preterm births and premature rupture of membrane [6, 32]. Although the mechanism behind these ghastly effects is still not clear but certain studies have described novel factors implicated in pathogenesis of HEV in pregnancy. Horvatitis *et al*. reported elevation of steroid hormones during pregnancy causes suppression of T cell mediated immunity which increases susceptibility to viral infections [33]. Recently, raised oestrogen level has emerged as a marker for maternal mortality in pregnant women infected with HEV [34].

Being the largest teaching and referral institute of the government sector, the number of critical and morbid patients are referred here with malnutrition and without any antenatal care is well reflected in the demographic profile of women in present study. Complications like DIC, PPH and fulminant hepatitis are life threatening. Considering the complexities of treatment in women with HEV infection where many drugs are contraindicated and surgical recourse is often not feasible causing higher morbidity as well as mortalities due to primary PPH in these cases. Considering the fact of a worst prognosis, a special emphasis was laid on use of condom balloon tamponade from 2015 in the department.

The study showed the remarkable effectiveness (100%) of C-UBT in preventing and treating PPH in women with HEV infection. In a similar type of study by M Siddiqui and M Rashid in Bangladesh, 40 pregnant women with jaundice were recruited and prophylactic uterine balloon was inserted to arrest primary PPH [35]. Their results showed ≥90% success rate of balloon tamponade. Many other studies also had similar results [18, 24-27, 31]. In our study, C-UBT controlled the intractable haemorrhage also due to coagulopathy (OR<1, P=0.01), severe anaemia (OR<1) and hepatic encephalopathy (OR<1) [19, 21]. Prevention from PPH along with supportive measures improved the general condition of the women as reflected by lesser mortality (OR<1), lesser number of days in ICU (OR<1) and hospital stay and a greater number of women discharged. These findings are in accordance with others [20, 22, 24]. Over and above these benefits, our study adds to the growing body of evidences in which use of C-UBT significantly reduced the requirement of invasive procedures like compression sutures, pelvic devascularisation and obstetric hysterectomy [12-15] (OR<1, P=0.1). Avoiding obstetric hysterectomy also avoids the psychosocial consequences of loss of uterus and fertility in a young woman. This data will motivate clinicians at various levels of facilities in low resource setting to attempt use of C-UBT for prevention and treatment of PPH in women with HEV infection and thereby saving their lives and families.

Table 1: Sociodemographic factors in pregnant women with hepatitis e

Characteristics	Study group (n=20)	Control group (n=20)
AGE (in years) mean+2SD	25.3+0.64	26.3+1.5
Parity (mean+2SD)	2.5+1.9	2+0.43
Educational Status		
1.uneducated	3(15%)	4(20%)
2.primary education	1 (5%)	2(10%)
3.secondary education	11 (55%)	7(35%)
4.higher secondary	3(15%)	6(30%)
5.graduate and post graduate	2 (10%)	1(5%)
Occupation		
1.working	3 (15%)	4(20%)
2.non working	17 (85%)	16(80%)
Residence		
1.Urban	15 (75%)	12(60%)
2.rural	5 (25%)	8(40%)
Booking Status		
1.Booked	9(45%)	2(10%)
2.Unbooked	11(55%)	18(90%)
REFFERAL	13(65%)	17(85%)

Table 2: Labour findings in study and control group women.

Labour Characteristics	Study group(n=20)	Control group(n=20)
Type of pregnancy		
a. singleton pregnancy	17(85%)	19(95%)
b. multiple pregnancy	3(15%)	1(5%)
Gestational age on admission (in weeks) mean+2SD	32.7+1.2	32.6+1.8
According to gestational age		
a. term	3(15%)	15(75%)
b. preterm	17(85%)	5(25%)
c. post term	0	0

Onset of labour		
a. spontaneous	16(80%)	10(50%)
b. induced	4(20%)	4(20%)
Mode of delivery		
a. vaginal	20(100%)	14(70%)
b. caesarean section	0	6(30%)
c. instrumental	0	0
Baby weight in kg (mean+2SD)	1.9+0.17	1.9+0.17

Table 3: Relation of balloon tamponade with maternal complications Number of Women

Complications	Study Group (n=20)	Control Group (n=20)	OR, 95%CI, P-value
PPH	8	16	0.16(0.04-0.68), P=0.01 OR<1 highly significant
DIC	2	5	0.33(0.056-1.97) OR<1 highly significant
Severe anaemia	3	6	0.4(0.08-1.95) OR<1 highly significant
Hepatic encephalopathy	1	2	0.4(0.03-5.6) OR<1 highly significant
Hypertensive disorders	4	4	1(0.21-4.7) OR=1 equivocal
Invasive procedures	0	4	OR=0.08(0.004-1.7) P=0.11 OR<1 highly significant
ICU admission	9	20	OR=0.02(0.001-0.3) P=0.009 highly significant
Mortality	6	14	OR=0.18(0.04-0.71) P=0.01 highly significant

Invasive procedures include compression sutures, uterine artery ligation, internal iliac artery ligation and obstetric hysterectomy. CI is Confidence Interval.

Table 4: Comparison of lab parameters and peripartum factors in study and control group.

Factors (mean+2SD)	Study Group N=20	Control Group N=20
Pre delivery Hb(g/dl)	8.7+0.86	8.09+1.08
Post-delivery Hb(g/dl)	7.8+0.58	7.5+0.81
platelet count at delivery (/mm^3)	212000+23.8	170000+25.4
Coagulation profile		
Prothrombin time(secs)	16.6+2.3	21.3+3.5
INR (secs)	1.7+0.36	2.0+0.3
Liver function tests		
a. Serum total bilirubin(g/dl)	8.2+2.3	12.4+2.5
b. Direct bilirubin(g/dl)	5.9+1.8	8.1+1.9
c. SGOT	229+81.2	548+141.7
d. SGPT	181+73.6	219+62.3
FFP transfusion	6.3+2.9	11.8+3.1
Blood transfusion	2.4+1.7	3.4+2.1
No of days of ICU admission (mean+2SD)	1.75+0.80	8.4+0.9
No of days of hospital stay (mean+2SD)	5.3+1.09	8.2+1.6

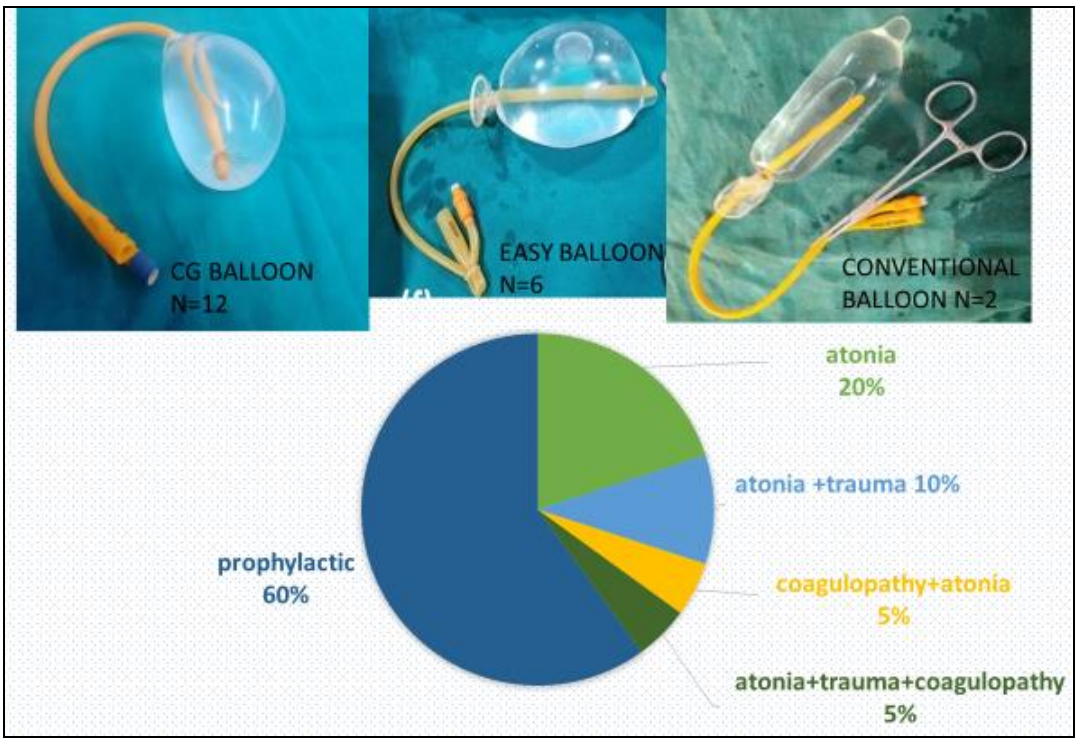

Fig 1: Indications of balloon tamponade in study group.

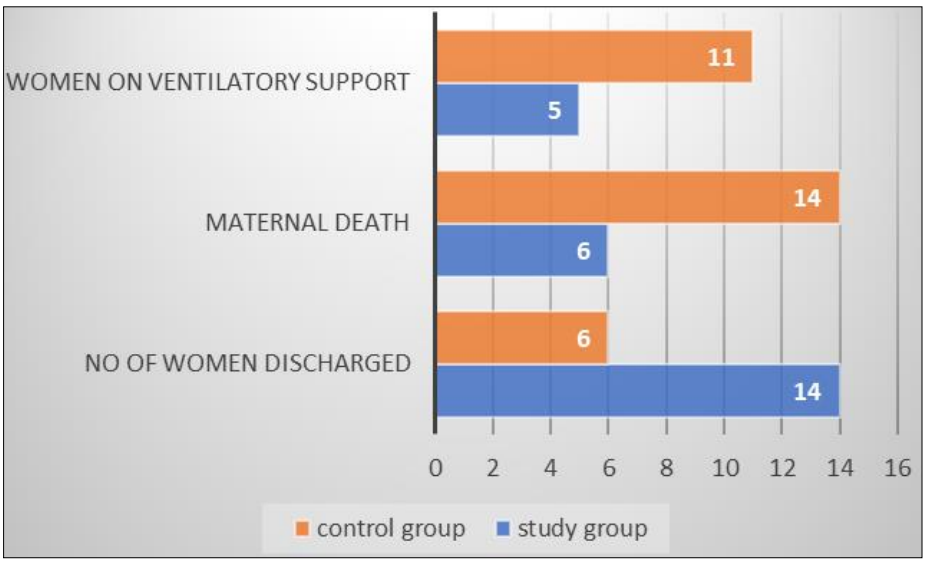

Fig 2: Maternal outcome in pregnancy with hepatitis e (with and without balloon tamponade).

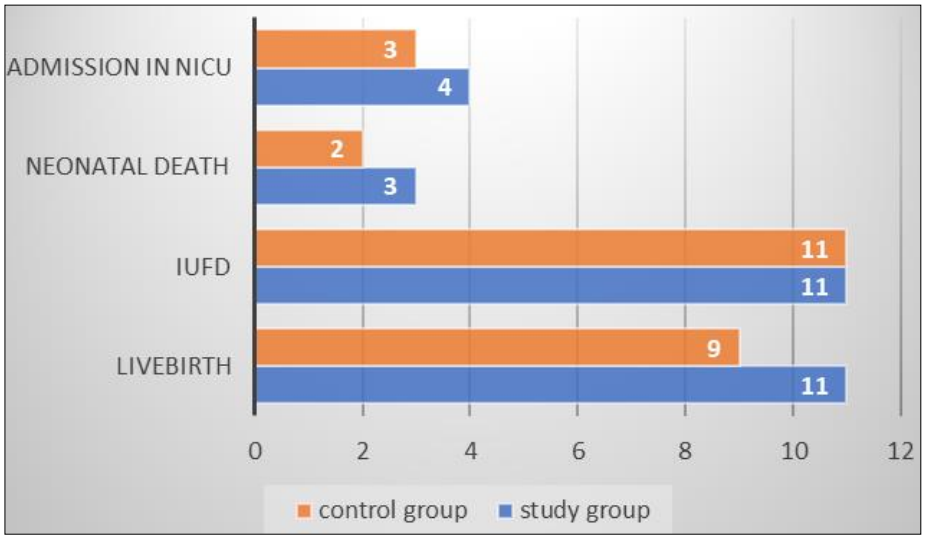

Fig 3: Foetal outcome in women with hepatitis e with and without balloon tamponade.

Conclusion

In our study, the prophylactic as well as therapeutic use of low-cost condom balloon tamponade at low resource settings in women having HEV infection and delivering has proved very safe, effective and low-cost endeavour. Routine use of this, easy and prepared at the point of care device can go a long way to improve morbidity associated with PPH which is a known complication in pregnancy with HEV infection.

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Declarations

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Conflict of interest: None declared
Ethical approval: Not required

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