Original Article
Pak Armed Forces Med J 2016; 66(Suppl):S117-22

COMPARISON OF B-LYNCH SUTURE VS SYNTOCINON INFUSION FOR POSTPARTUM HEMORRHAGE PROPHYLAXIS IN CARDIAC PATIENTS UNDERGOING CESAREAN SECTION-A RANDOMIZED CLINICAL TRIAL

Asma Ansari, Kaleem Ahmed, Hafsa Khalil

Armed Forces Institute of Cardiology/National Institute of Heart Diseases Rawalpindi, Pakistan

ABSTRACT

Objective: To compare the efficacy and safety of syntocinon infusion and B-Lynch suture application for postpartum hemorrhage prophylaxis in cardiac patients.

Study design: Randomized clinical trial.

Place and duration of Study: This study was conducted at obstetrics and gynecology ward of Armed Forces Institute of Cardiology/National Institute of Heart Disease (AFIC-NIHD) from Jan 2015 Dec 2015.

Methodology: All the eligible patients undergoing cesarean section at AFIC-NIHD were included. Primary outcome measure was primary postpartum hemorrhage requiring additional measures. Secondary outcome was difference in hemoglobin level and hemodynamic status between two groups. Safety was assessed by development of cardiac complications like pulmonary edema, arrhythmias and ischemia.

Results: A total of 45 patients were randomized to either low dose syntocinon group or B-lynch group. Mean age of our study population was 27.16 ± 4.57. Parity between two groups was in-significant (p=0.46), most of the patients were of parity2 i.e. 16 (35.6%). Of all the patients 32 (71.7%) had acquired heart disease,9(20%) congenital and 4(8.9%) rhythm disorders. Post partum hemorrhage in group A was 5 (71.4%) and group B was 2(28.5%),P=1.000.Blood pressure and heart rate changes with intervention were statistically significant between group A and B. Cardiac complications between two groups were arrhythmias(P=0.670),ischemia (p=1.000), pulmonary edema (p=0.157) and cardiac arrest (p=1.000).

Conclusion: Cardiac patients are unique, considering their hemodynamic status and limitation in treatment options. This combined with a life threatening complication like postpartum haemorrhage can be a catastrophe. So in these high risk patients prophylaxis should be a norm rather than waiting for the complication to happen.

Keywords: Cardiac disease, Postpartum hemorrhage, Syntocinon.

INTRODUCTION

Postpartum hemorrhage (PPH) is a life-threatening obstetric emergency that occurs after caesarean section or normal vaginal delivery. It is defined as ≥ 500mL hemorrhage after vaginal or ≥1000mL hemorrhage after cesarean section, and affects 1-5% of all deliveries[1,2].

The main causes of direct maternal deaths in developing countries including Pakistan are hemorrhage, hypertension, sepsis and miscarriage related complications[3]. Of the indirect causes of maternal death cardiac disease is the main contributor globally[4]. According to studies the incidence of clinically significant cardiac disease in pregnancy is between 0.9-3.8%[5]. Pregnancy poses a major hemodynamic burden in cardiac patients so risk of developing complications is increased as compared to normal population[6]. Cardiac patients are unique considering they cannot be given conventional drugs and anesthetic agents without adding to the risks[7]. Postpartum hemorrhage if occurs is detrimental to the fragile cardiovascular status of these high risk patients. Active management of third stage of labor (AMTSL) reduces the incidence of PPH but these cardiac patients require additional measures other than the standard AMTSL as majority of them are on anticoagulants and in delicate hemodynamic balance[8]. Prophylactic oxytocics should be routinely used in third

Correspondence: Dr Asma Ansari, Assistant Professor Obstetrics & Gynaecology AFIC/NIHD, Pakistan
Email: asmaansari31@gmail.com

stage labor as they reduce the risk of PPH by 60%[9]. According to guidelines of Royal college of obstetricians and gynecologists low dose syntocinon should be used for cardiac patients in cases of postpartum hemorrhage. Instead of repeating syntocinon and other oxytocics B-lynch application can be considered as it will bypass the hemodynamic effects of repeated doses of oxytocic drugs in these high risk patients , but its role in prophylaxis is still not clear[10]. Syntocinon the recommended drug for third stage management should be used with caution in cardiac patients due to their predisposition to rhythm disorders and myocardial ischemia as significant changes occur in blood pressure and heart rate after its administration especially when combined with anesthetic agents. Combined antidiuretic effect of oxytocin and intravenous fluid administration may cause fluid overload leading to a hemodynamic form of acute pulmonary edema[11]. Patients who remain undiagnosed during antenatal period are usually diagnosed peri operatively or in immediate postpartum period due to these complications. Due to limitation of drug options for PPH management and prophylaxis in cardiac patients B- Lynch suture seems a reasonable option. It is a form of compression suture used to mechanically compress the atonic uterus in face of PPH. It was first described by B-Lynch in 1997 for management of massive PPH when hysterectomy was not an option[12]. Over the passage of time, as its long and short term safety has been established its role in PPH prophylaxis has been studied and under consideration[13].

The aim of our study is to provide evidence for the use of syntocinon and brace suture in these high risk patients for prophylaxis of PPH thus saving obstetric and cardiac life threatening complications.

METHODOLOGY

This was a randomized clinical trial done at Armed Forces Institute of Cardiology National institute of heart disease (AFIC-NIHD), Pakistan from january 2015 to june 2015. Approval for conducting the study was taken from institutional review board and 45 patients were recruited in this study. During the study cardiac patients scheduled for emergency or elective cesarean section reporting to obstetrics department were randomized to receive low dose syntocinon infusion or b lynch suture after delivery of placenta. Those cardiac patients having placenta previa and hemodynamic instability were excluded. Written informed consent for the procedure was taken with detailed counseling of risks. As per protocol Women were randomly assigned to one of two groups

Table-1: Shows the demographic profile of groups.

Demographics			
Variables	**Group A (n=30)**	**Group B (n=15)**	***p*-value**
Age (mean + SD)	27.57 ± 4.56	26.33 ± 4.64	0.400
Parity n (%)			
P0	6 (100%)	0 (0%)	
P1	6 (66.6%)	3 (33.33%)	
P2	10 (62.5%)	6 (37.5%)	0.466
P3	6 (54.5%)	5 (45.45%)	
P4	1 (50%)	1 (50%)	
P5	1 (100%)	0 (0%)	
Cardiac disease n (%)			
Congenital	06 (66.6%)	03 (33.3%)	0.755
Acquired	22 (68.75%)	10 (31.25%)	
Rhythm disorder	02 (50%)	02 (50%)	
IND n (%)			
Elective	25 (67.57%)	12 (32.4%)	1.000
Emergency	05 (62.5%)	03 (37.5%)	

with a 2:1 allocation using simple randomization with computerized random numbers. Thirty patients were assigned to group A which received syntocinon and 15 to group B which received b- lynch suture. Routine management of third stage of labor was done by AMTSL in both groups according to standard recommendation of third stage of labor by giving[2]. Five IU syntocinon slow IV immediately after delivery of baby, delayed cord clamping, controlled cord traction and uterine massage. Group A was given prophylaxis by 5 IU syntocinon in 50 ml ringers lactate at 7 ml per hour for four hours postoperatively and group A was applied with B-Lynch suture with vicryl 1 by a blunt semicircular needle at four points on anterior and posterior uterine walls. Arterial line was passed in all these patients for measurement of systolic , diastolic blood pressure and heart rate preoperatively, 10 minute, one and four hours after the intervention. Mean blood loss was estimated by visual estimation, number of used swabs, and amount of aspirated blood. Patients requiring additional uterotonics, and transfusion were noted. Continuous postpartum bleeding and uterine atony judged by attending physician was considered a failure of intervention. Occurrence of postpartum hemorrhage and cardiac complications were the primary outcome measures. Occurrence of arrhythmias, ischemia, pulmonary edema and

Table-2: Characteristics of outcome variables in two groups.

Primary and secondary outcome			
Variables	**Group A (n=30)**	**Group B (n=15)**	***p*-value**
PPH n (%) Yes No	 05 (71.4%) 25 (65.79%)	 02 (28.5%) 13 (34.2%)	1.000
Uterine tone n(%) Good Average Poor	 19 (82.6%) 06 (46.1%) 05 (55.5%)	 04 (17.4%) 07 (53.8%) 04 (44.4%)	0.06
Transfusion n (%) Yes No	 04 (57.1%) 26 (68.4%)	 03 (42.8%) 12 (31.58%)	0.670
Additional measures n (%) Yes No	 11 (55%) 19 (76%)	 09 (45%) 06 (24%)	0.205
Difference in Hb (Mean + SD)	1.063 + 0.4047	1.387 + 0.5540	0.031
Pre OP heart rate (Mean + SD)	81.40 + 4.79	82.53 + 2.67	0.400
Heart rate after 10 min (Mean + SD)	89.9 + 9.04	81.33 + 1.63	0.001
Heart rate after 1 hr (Mean + SD)	84.67 + 3.03	83.60 + 2.53	0.248
Heart rate after 4 hr (Mean + SD)	83.73 + 3.81	83.20 + 2.24	0.621
Pre OP Arterial BP systolic(Mean + SD)	123.3 + 6.609	121.3 + 9.15	0.406
Pre OP Arterial BP diastolic (Mean + SD)	78.3 + 6.47	78.6 + 6.39	0.871
Arterial BP after 10min systolic (Mean + SD)	114.0 + 6.215	127.3 + 5.93	0.000
Arterial BP after 10min diastolic (Mean + SD)	69.6 + 4.13	76.66 + 6.17	0.001
Arterial BP after 1hr systolic (Mean + SD)	117 + 7.49	122 + 5.606	0.028
Arterial BP after 1hr diastolic (Mean + SD)	72.6 + 4.49	76.6 + 4.88	0.009
Arterial BP after 4hr systolic (Mean + SD)	114.3 + 5.68	122.6 + 5.93	0.000
Arterial BP after 4hr diastolic (Mean + SD)	71.33 + 3.46	79.3 + 4.57	0.000

cardiac arrest was noted in both groups for a 24 hour observation period. Secondary outcomes were hemoglobin difference assessed by pre and post operative hemoglobin difference 24 hours after surgery and hemodynamic parameters between two groups. Data collection tool was developed to measure the demographics, clinical findings, complications and final outcome of patients. Data entries were done on SPSS and descriptive statistics were applied for qualitative and quantitative variables by using SPSS version 22. Chi-square test and independent sample T-test were used to calculate the p-values. *p*-value of <0.05 was considered to be significant.

RESULTS

To our best knowledge no earlier study on comparison between these two interventions in cardiac patients has been done. Total of 30 patients in group A and 15 in group B were recruited. Mean age was 27.1 ± 4.57 yrs.13.3% were primigravida. Parity between two groups was in-significant (p=0.46), 16 (35.6%) of the patients were P2; 11 (24.4%) p3, 9 (20%) P1, 6 (13.3%) P0, 2 (4.4%) P4 and only 1 (2.2%)P5. Acquired heart diseases account for 32 (71.1%), congenital heart disease 9 (20%) and rhythm disorders 4 (8.9%).indication for cesarean section was elective in 37 (82.2%) and emergency in 8 (17.8%).Difference in age parity and indication was not statistically significant between two groups as shown in table 1.primary outcome postpartum hemorrhage was judged by blood loss, uterine tone and need for transfusion. pre and post operative hemoglobin difference was 1.063 ± 0.40 and 1.387 ± 0.554 which was not significant between two treatment modalities. Hemodynamic evaluation by blood pressure and heart rate measurement was done and hypotension after low dose syntocinon occurred along with increase in heart rate. B-Lynch suture patients did not experience these hemodynamic changes as shown in table-2.

Safety was assessed by occurrence of cardiac complications which were not statistically significant between group A and B. Cardiac complications between two groups were arrhythmias (p=0.670), ischaemia (p=1.000), pulmonary edema (p=0.157) and cardiac arrest (p=1.000) as shown in -1.

DISCUSSION

Maternal deaths as a result of the classic causes of hemorrhage, hypertension abortions and infection are still a reality in this part of the world. In the western world as well as low and middle income countries the relative importance of cardiac disease has increased as more and more children having congenital heart disease are surviving into adult hood and contemplating child birth and acquired causes still remain a huge burden in developing world[14]. The commonest cause of heart disease is still rheumatic in developing countries like Pakistan as is the result in our study 71.1% cases and also, in other studies done here[15,16]. The major burden is congenital heart disease in western countries[17]. Demographic profile

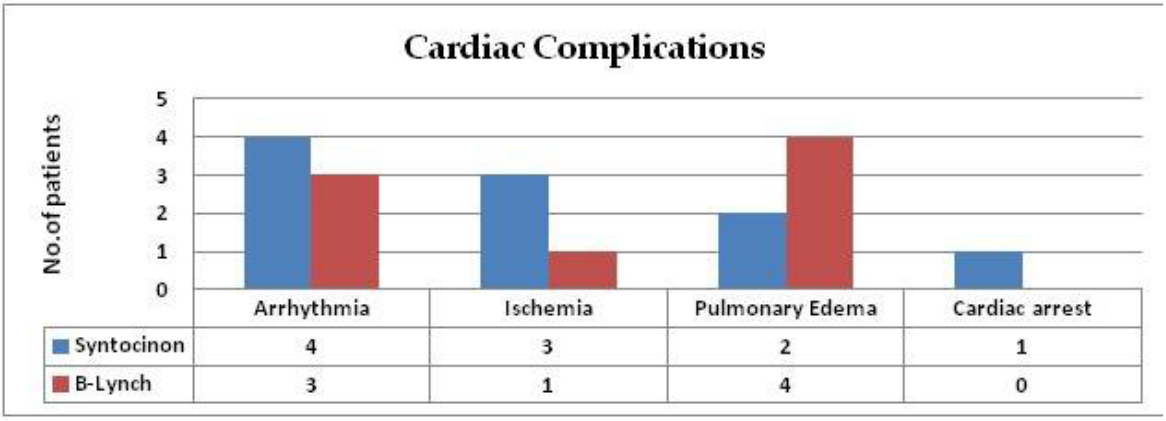

Figure-1: Frequency of cardiac complications in both groups.

including age, parity, indication for cesarean section of the patients was similar in both groups and comparable to other studies done on post partum hemorrhage prophylaxis[18]. In developing countries PPH contributes between 17% to 40% of maternal mortality and 40% of maternal morbidity 19. In countries like Pakistan where severe anaemia and cardiopulmonary disease is common, a loss of as little as 250 ml may constitute a clinical problem. Hence it becomes more important to prevent any avoidable blood loss in women who are at high risk of PPH. Majority of the studies done on oxytocin influence have cardiac patients in their exclusion criteria as due to their vulnerable hemodynamic status the effects of these drugs can be catastrophic in standard doses. In a study comparing different options for PPH management in spite of demographic profile similar to this study in the syntocinon group 13-16% required additional oxytocins, 1.6% had PPH and there was need for transfusion in 0.5%[20]. In this study even with lower dose of syntocinon heart rate and blood pressure changes occurred which improved with time, and comparison with group B revealed stable vital signs and less blood loss as compared to syntocinon group. In non cardiac patients studies show a better profile for low dose intravenous syntocinon like in our study and PPH was 1 %with additional uterotonics needed in only 3% patients and no patient needed transfusion[21]. Recently focus is concentrated on prevention of PPH. Active management of the third stage by intramuscular or intravenous injection of oxytocin is practiced for a long time. Other prophylactic measures are on trial. Misoprostol a cheap and stable drug has emerged as an alternative drug for management of third stage of labor. Surgical prophylaxis in the form of balloon occlusion or arterial catheterization to reduce intraoperative blood loss is being tried in cases of placenta previa[22] . Need for prophylactic oxytocic infusion after delivery in presence of risk factors is considered in a study which revealed comparable results to this study[23]. Elective B-Lynch suture is described during caesarean section in parturient with congenital heart disease, to avoid the need for oxytocin and to prevent atony of uterus[24]. In our syntocinon group patients required transfusion and additional uterotonics. A study by Ghazala et al on postpartum hemorrhage prophylaxis by syntocinon or ergometrine reported transfusion in 2% of patients. PPH in syntocinon group was 10% and in ergometrine was 1.5% and surgical intervention was more in syntocinon group. Hemoglobin difference in our study between pre and post operative patients was almost comparable to non cardiac patients which was 0.8 g/dl. 25 ,26 In a study done by Larciprette et al inspite of having cardiac patients in exclusion criteria showed similar hemodynamic changes with syntocinon,a fall in blood pressure and tachycardia immediately after syntocinon injection as compared to carbetocin. Hemoglobin decrease was 1.1g/dl and additional oxytocics were required[27]. Individual small studies and case series on B lynch suture application show a better profile in managing PPH but need for uterotonics was less as compared to this study which is probably confounded by its application in patients who have already received multiple uterotonics due to massive PPH. In this study average age of patients was 20 years unlike our study. There is no transfusion and no complication during or six months after procedure. No additional uterotonics except IU syntocinon for active management of third stage or surgical procedure was done. Hemoglobin difference pre and post op was 0.4-1.8 g/dl[13]. Cardiac complications reported in studies on pregnant cardiac patients were similar[28]. Taking inspiration from Professor B-Lynch's statement in the last two sentences of the conclusion in his original article on B-lynch suture published in BJOG in 19970 that" cost-effectiveness of this procedure may encourage developing countries to consider its application where necessary both for prophylactic and therapeutic purposes" this small study was under taken. B-Lynch suture is tested and tried with successful outcome in around 1800 cases in management of severe postpartum haemorrhage since 1989[29,30]. The technique of B Lynch suture is quick and takes extra four minutes only. We did not find any intra or post partum complications of the

technique although in literature partial ischemic necrosis is reported as a rare complication of the procedure[31].

Major contribution of our study is that it is a randomized trial between these two prophylactic options and the results justify a larger trial to accurately quantify the response rate. So that cardiac patients can get some clear guidelines on managing this life threatening complication.

Limitation of this study is small study cohort, but even recruiting these cardiac patients with variety of cardiac lesions and pregnancy became possible as this is a tertiary care cardiac centre catering to all kinds of cardiac patients.

CONCLUSION

This small study was performed with intention of determining whether or not elective B-Lynch suture is effective in preventing PPH in women undergoing caesarean section who are at high risk for hemorrhage and cardiovascular complications and also prophylactic role of syntocinon infusion for PPH. Immediate hemodynamic effects can lead to cardiac complications if not managed promptly. As our patients were managed in a well equipped cardiac operation theatre so the risks were reduced. B- lynch suture application is a reasonable option in cardiac patients as it is associated with less hemodynamic changes.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

REFERENCES

1. World Health Organization. Recommendations for the prevention and treatment of postpartum haemorrhage. WHO; 2012. www.who.int/reproductive health/ publications/ maternal_perinatal_health/9789241548502.
2. FIGO Guidelines: Prevention and treatment of PPH in low resource settings: Int J of Gynecology and Obstetrics;117(2012)108-18
3. Khan K et al. WHO analysis of causes of maternal death: A systematic review.367 (9516):1066-74.
4. Bhatla N, Lal S, Behera G, Kriplani A, Mittal S, Agarwal N,et al. Cardiac disease in pregnancy. Int J Gynaecol Obstet.2003;82(2):153-59.
5. Nickens M, Long R, Geraci S. Cardiovascular disease in pregnancy. South Med J. 2013;106(11):624-30.
6. Mitra J, Bhattacharyya P, Roy J , Karim R. Significance of Hemodynamic Monitoring in Peri operative and Critical Care Management in Obstetric Practice. http://www.astrocyte.in on Tuesday, December 01, 2015, IP: 124.109.48.36]
7. VandenBosch AE, Ruys TP, Roos-Hesselink JW. Use and impact of cardiac medication during pregnancy. Future cardiology 2015;11(1):89-100.
8. Gülmezoglu AM, Lumbiganon P, Landoulsi S, Widmer M, Abdel-Aleem H, Festin M, et al. Active management of the third stage of labour with and without controlled cord traction: a randomized, controlled, non-inferiority trial. Lancet. 2012;379:1721–7.
9. Mousa HA,Blum J,Abou Elsenoun G,et al.Treatment for primary PPH. Cochrane Data Base systematic review.2014.Feb 13;2:CD 003249.
10. Guideline No.13: Cardiac disease and pregnancy: RCOG. 2011. Available from: http://www.rcog.org.uk/files/rcogcorp/Good Practice 13 Cardiac Disease and Pregnancy.pdf
11. Moertl MG, Friedrich S, Krashl J, Wadsack C, Lang U,Schlembach D. Haemodynamic effects of carbetocin and oxytcin given as intravenous bolus on women undergoing caesarean delivery: a randomised trial. B J Obstet and Gynaecol 2011; 118:1349-56.
12. B-Lynch surgical technique for the control of massive postpartum haemorrhage: an alternative to hysterectomy? Five cases reported. BJOG , March 1997,104;372-5.
13. Vacnnari M,Virknd. A.Prophylactic B-Lynch Suture During Emergency Caesarean Section In Women At High Risk Of Uterine Atony: A Pilot Study.Int J of Gynae Obst.7(1).1-5
14. Regitz-Zagrosek V, Blomstrom Lundqvist C, Borghi C, Cifkova R, Ferreira R, Foidart J-M, et al. ESC Guidelines on the management of cardiovascular diseases during pregnancy :European Society of Cardiology (ESC) The Task Force on the Management of Cardiovascular Diseases during Pregnancy European Heart Journal.2011;32(24):3147-97.
15. .Yasmeen N,Aleem M,Iqbal N.Feto maternal out come in patients with cardiac disease in pregnancy. Pak J Med Health Sci .Oct-Dec 2011;5(4):748-51
16. .Mazhar SB,Gul-e-Irum. Fetomaternal Outcome in pregnancy with Cardiac Disease. J Coll Phys Surg Pak 2005 Aug; 15(8):476-80
17. .Roos-Hesselink J W, Ruys TP, Stein JI, Thilén U, Webb GD, Niwa K, et al. Outcome of pregnancy in patients with structural or ischaemic heart disease: Results of a registry of the European Society of Cardiology. Euro Heart J. 2013;34:657-65.
18. Royal College of Obstetricians and Gynaecologists. Prevention and management of postpartum hemorrhage. Guidelines no 52 London: RCOG; 2009.
19. Westhoff G, Cotter AM, Tolosa JE. Prophylactic oxytocin for the third stage of labor to prevent postpartum hemorrhage. Cochrane Database Syst Rev. 2013;10:CD001808.
20. Su L, Rauff M, Chan Y, Mohamad Suphan N, Lau T, Biswas A, Chong Y. Carbetocin versus syntometrine for the third stage of labor following vaginal delivery—a double-blind randomized controlled trial. BJOG 2009;116:1461-66.
21. Megha S,Parneet K,Khushpreet K.A comparative study of oxytocin/misoprostol/methylergometrine for active management of third stage.Journal of Obs Gynae India.May-June 2014.64(3):175-9.
22. Attilakos G, Psaroudakis D, Ash J, Buchanan R, Winter C,Donald F, et al. Carbetocin versus oxytocin for the prevention of postpartum haemorrhage following caesarean section:The results of a double-blind randomized trial. BJOG 2010;117:929-36.
23. Svanstrom MC, Biber B, Hanes M, Johansson G, Naslund U,Balfors EM. Signs of myocardial ischemia after injection of oxytocin and methylergometrine during caesarean section.Br J Anaesth 2008; 100:683-89.
24. Dob.D.P, Yentis.S.M. Practical management of the Parturient with congenital heart disease: international Journal of Obstetric Anaesthesia (2006) 15,137-44.
25. Mahmud G ,Javaid K,Tasnim N,Tabassum A,Bangash K. Where does ergometrine stand in prevention of postpartum hemorrhage in cesarean section. J Pak Med Assoc.Aug 2014;64(8):911-4.
26. Rajaei et al.Safety and efficacy of misoprostal versus oxytocin for the prevention of Post partum hemorrhage. J of Pregnancy.vol 2014 art ID 713879;1-4.
27. Larciprette et al.Carbetocin vs oxytocin in caesarean section with high risk of post partum hemorrhage. J of Prenatal Med 2013:7(1):12-8
28. Burt C, Durbridge J. Management of cardiac disease in pregnancy. Cont Edu Anaesth Crit Care and Pain.2009;9(2):44-8
29. Holtsema H, Nijland R, Huisman A. The B-Lynch technique for postpartum hemorrhage: An option for every gynaecologist. Eur J Obstet Gynecol Reprod Biol 2004;115:39–42.
30. Api M, Api O, Yayla M. Fertility after B-Lynch suture and hypogastric artery ligation. Fertil Steril 2005;84:509.
31. Price N, Lynch CB. Uterine necrosis following B-Lynch suture for primary postpartum haemorrhage. BJOG.Nov 2006 ;113:1341