### P-01

#### Thromboembolism prophylaxis after cesarean section (PRO-CS) trial

<u>F.H. AlGahtani</u><sup>1\*</sup>, H. Al-Dohami<sup>2</sup>, S. Abo-Harbesh<sup>3</sup>, A. Al-Gader<sup>4</sup>, A. Aleem<sup>5</sup> <sup>1</sup>Hematology Consultant, Medicine Department, King Saud University Hospital, Riyadh, Saudi Arabia; <sup>2</sup>Obgyne Consultant, Obgyne Department, Security Forces Hospital, Riyadh, Saudi Arabia; <sup>3</sup>Hematology Consultant, Hematology Department, Security Forces Hospital, Riyadh, Saudi Arabia; <sup>4</sup>Physiology Consultant, Physiology Department, King Saud University Hospital, Riyadh, Saudi Arabia; <sup>5</sup>Hematology Consultant, Medicine Department, King Saud University Hospital, Riyadh, Saudi Arabia

\*E-mail: falgahtani@ksu.edu.sa

**Background:** Pregnancy and the post partum are well-established risk factors for venous thromboembolism, with higher risk if delivered via cesarean section. However, current evidence cannot justify deep vein thrombosis thromboprophylaxis on the basis of caesarean section alone in all women with different risk factors especially low risk, thus cannot be recommended for the time being. This study was conducted to determine the efficacy and safety of DVT prophylaxis in low risk women who delivered via cesarean section, and to identify the risk factors. The study registered in clinical trial, NCT01321788.

**Methods:** Prospective, randomized study of adult female patients aged 18–35 years old presenting to OB-Gyn Department of Security Forces hospital, Riyadh Saudi Arabia who delivered via cesarean section were included in the study. Subjects were randomized into two groups; a) Drug group – received Tinzaparin 4500 IU subcutaneously once daily 12–24 hours after cesarean operation and, b) placebo group – received once daily 12–24 hours after cesarean operation for tow weeks. Both groups received mechanical prophylaxis using graduated compression stockings. Patient's demographics, physical data, obstetrical history, medical histories for thrombosis and co-morbidities were all noted. Laboratory tests were done to all patients. Patients were observed within one week of hospital stay for signs and symptoms of DVT, minor and major bleeding events. After discharge, patients followed-up after two weeks, at 6th week, at 3rd month and 6 months interval thereafter for one year.

**Results:** A total of 200 patients (mean age: 28.6 years) consented for the study. The demographic data was similar to both groups. There were only one incidences of deep vein thrombosis in the 200 placebo group in comparison to 100 tinzaparin study group. There had been no record of death after 1 year of follow-up.

**Conclusion:** Our study showed the low risk caesarian section are not at risk of developing DVT as no benefits of LMWH will confirm no safety and efficacy of thromboprophylaxis using LMWH.

### P-02

### Effects of new oral anticoagulants (NOAC) on different antithrombin assavs

E.-M. Norberg<sup>1</sup>, L. Söderblom<sup>1</sup>, M. Berndtsson<sup>1</sup>, M. Skeppholm<sup>2</sup>, J. Antovic<sup>1</sup>

<sup>1</sup>Department of Coagulation Research, Institute for Molecular Medicine and Surgery, Karolinska Institutet, & Department of Clinical Chemistry, Karolinska University Hospital, Stockholm, Sweden; <sup>2</sup>Department of Medicine, Clinical Pharmacology Unit, Division of Cardiovascular Medicine, Karolinska Institutet & Danderyd Hospital, Stockholm, Sweden

**Background:** Antithrombin (AT) is an inhibitor of different coagulation factors, primarily thrombin and factor Xa. Inherited deficiency of AT is relatively rare, but acquired deficiency is far more common and is associated with liver disease, sepsis, nephrotic syndrome and consumption coagulopathy. AT activity is measured with chromogenic methods based on inhibition of either thrombin or factor Xa. It has been shown (primarily *in-vitro*) that new oral anticoagulants (NOAC) which are based on direct inhibition of thrombin (dabigatran) or factor Xa (rivaroxaban, apixaban) may influence thrombin and factor Xa based assays for determination of AT respectively, overestimating the AT level. We have tested the effects

of NOAC on both thrombin and factor Xa based AT assays in plasma from patients treated with these drugs in real life settings.

**Method:** Plasma from patients treated with dabigatran (n=30), rivaroxaban (n=20) and apixaban (n=17) were tested for AT activity using thrombin and factor Xa based methods (Berichrom ATIII and Innovance Antithrombin, Siemens Healthcare Diagnostics). Plasma concentrations of drugs varied between 8–172  $\mu$ g/L for dabigatran, 8–437  $\mu$ g/L for rivaroxaban and 36–178  $\mu$ g/L for apixaban.

**Results:** In plasma from patients treated with rivaroxaban or apixaban, AT results determined with the factor Xa based assay were higher than results from the thrombin based assay (up to 70% and 44% for rivaroxaban and apixaban respectively). The increase in AT activity correlated to the drug concentration ( $r^2$ =0.943 and 0.839, for rivaroxaban and apixaban respectively, p<0.0001). In plasma from patients treated with dabigatran, we observed no systematic effect on the AT results.

**Conclusion:** Our results suggest that the risk of overestimating AT is greater for patients treated with rivaroxaban or apixaban if a factor Xa based assay is used, compared to patients treated with dabigatran when a thrombin based assay is used. Preferably, each lab should have access to both thrombin and factor Xa based assays.

#### P-03

### Management of major obstetric haemorrhages over a 10-year period using an acute massive blood loss (AMBL) protocol

J. Garry<sup>1\*</sup>, J. McNamee<sup>2</sup>, A. Fortune<sup>1</sup>, M. McCloy<sup>1</sup>, J. Sargent<sup>1</sup>

<sup>1</sup>Haematology and; <sup>2</sup>Haemovigilance, Our Lady of Lourdes Hospital, Drogheda, Co. Louth, Ireland

\*E-mail: jennifergarry13@gmail.com

**Objective:** The aim of this study was to assess the efficacy of our Acute Massive Blood Loss (AMBL) Protocol in the management of major obstetric haemorrhage since it's introduction in 2005.

**Methods:** A retrospective analysis of patients experiencing major obstetric haemorrhage over the last 10 years was performed.

**Results:** 61 patients were identified as having a major obstetric haemorrhage between 2005 and 2014. The rate of major obstetric haemorrhage/1000 live births was calculated at 0.18%. 58% were delivered by C-section (33% emergency vs 25% elective). Uterine atony (32.8%), retained products of conception (23%) and placenta praevia/placenta acreta/placental abruption (21%) were the main causes identified. The mean EBL (estimated blood loss) and RCC (red cell concentrate) transfused were 3271 mL and 5 units respectively. With regard to outcomes, 93% of events were recorded as being well managed in the subsequent debriefings. 18% required admission to either ICU (9.8%) or HDU (8.2%). 9.8% required hysterectomy. The rate of maternal mortality due to haemorrhage was calculated at 1.6% (1 maternal death/10 years).

**Conclusion:** Early activation of the AMBL protocol has resulted in effective management of obstetric haemorrhage in our Hospital with low maternal mortality rates and low ITU admission rates. Mandatory debriefing sessions have enhanced learning from these events and facilitated standardization of practices and improvements in care.

### P-04

# Validation of screening tool for bleeding disorders in women with heavy menstrual bleeding

<u>S. Wiewel-Verschueren</u><sup>1,2\*</sup>, H.M. KnolD<sup>2</sup>, A.B. Mulder<sup>3</sup>, E.R. Klinkert<sup>2</sup>, H.C. Kluin-Nelemans<sup>1</sup>, A.G.J. van der Zee<sup>2</sup>, K. Meijer<sup>1</sup> <sup>1</sup>Division of Thrombosis and Haemostasis, Department of Hematology; <sup>2</sup>Department of Obstetrics and Gynecology; <sup>3</sup>Department of Laboratory Medicine, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands \*E-mail: s.wiewel@umcg.nl

**Introduction:** Women with heavy menstrual bleeding (HMB) are at an increased risk of a bleeding disorder. It would be efficient and decrease costs if one could predict who should be tested for haemostatic defects. Philipp et al. [1] developed a screening tool based on HMB, a history of anemia treatment, family history of bleeding disorder and non-HMB bleeding symptoms. This tool had a sensitivity of 89%. However, this screening tool has not yet been validated in other groups.

**Objective:** To validate Philipp's [1] screening tool in Dutch women with HMB.

**Material & Methods:** We included 192 consecutive patients with regular HMB (Pictorial Bleeding Assessment Chart-score >100). Gynecological examination was performed, blood was withdrawn and a questionnaire – including the markers of Philipps\* screening tool – was filled out.

**Results:** 52 patients (27%) had a bleeding disorder defined as platelet function defects, decreased fibrinogen, decreased von Willebrand factor, and/or factor VIII, IX, XI, XII deficiencies. In our cohort the screening tool is less sensitive than in the American cohort (see Table 1), and specificity remains low. Positive likelihood ratio was 0.96, negative likelihood ratio 1.03. The tool did not perform better if the analysis was limited to the women without gynecological abnormalities.

Table 1. Validation of screening tool.

Dutch cohort (n=192)	American cohort (n=217) [1]
67	89
30	16
26	72
71	37
	Dutch cohort (n=192) 67 30 26 71

**Conclusion:** The screening tool for haemostatic disorders is not useful in Dutch women with heavy menstrual bleeding. A better predictive screening tool is needed.

#### **Reference:**

 PhilippCS, et al. Evaluation of a screening tool for bleeding disorders in a US multisite cohort of women with menorrhagia. Am J Obstet Gynecol 2011;204:209.e1–7.

#### P-05

### Thyroid function in women with heavy menstrual bleeding

<u>S. Wiewel-Verschueren</u><sup>1,2\*</sup>, H.M. KnolD<sup>2</sup>, A.B. Mulder<sup>3</sup>, E.R. Klinkert<sup>2</sup>, H.C. Kluin-Nelemans<sup>1</sup>, A.G.J. van der Zee<sup>2</sup>, K. Meijer<sup>1</sup>

<sup>1</sup>Division of Thrombosis and Haemostasis, Department of Hematology; <sup>2</sup>Department of Obstetrics and Gynecology; <sup>3</sup>Department of Laboratory Medicine, University of Groningen, University Medical Center Groningen, Groningen, the Netherlands

\*E-mail: s.wiewel@umcg.nl

**Introduction:** Heavy menstrual bleeding (HMB) can be a manifestation of a systemic disease, such as a bleeding disorder or hormone imbalance. In clinical practice thyroid function is often tested, although guidelines do not endorse this, and strong evidence of thyroid function in HMB is lacking.

**Objective:** To evaluate the thyroid function in women with objectively estimated HMB.

**Material & Methods:** We included 192 consecutive patients with regular HMB (Pictorial Bleeding Assessment Chart-score (PBAC) > 100). In the first week after menstruation a gynecological examination was performed and blood was withdrawn. In 184 patients TSH and FT<sub>4</sub> were measured. Data from the Nijmegen Biomedical Study [1] were used as reference.

**Results:** The included patients with evident HMB had a median PBAC-score of 270 (Q1–Q3: 209–450) and 35% had anemia (Hb <7.5 mmol/L). Overt hypothyroidism (TSH >4.0 mU/L; FT<sub>4</sub> <11.0 pMol/L) was not seen in the patients, as opposed to in 0.6% of the reference group (p=0.29). In both patients and the reference group subclinical hypothyroidism (TSH >4.0 mU/L; FT<sub>4</sub> ≥11.0 pMol/L) was present in 4.9% (p=0.99). Overt (TSH <0.5 mU/L; FT<sub>4</sub> >19.5 pMol/L) and subclinical (TSH <0.5 mU/L; FT<sub>4</sub> ≤19.5 pMol/L) hyperthyroidism was found in 1.1% and 2.2% of patients, vs 0.6% (p=0.39) and 1.2% (p=0.22) in the reference group, respectively.

Also, no significant differences in thyroid function were seen between patients with and without gynecological abnormalities or those with and without coagulation disorders.

**Conclusion:** Thyroid dysfunction occurs in women with heavy menstrual bleeding, but to the same extent as in the general population. Thyroid function should not be routinely measured in women with HMB. **Reference:** 

#### Reference:

 Hoogendoorn EH, et al. Thyroid function and prevalence of antithyroperoxidase antibodies in a population with borderline sufficient iodine intake: influences of age and sex. Clin Chem 2006 Jan;52(1):104– 11.

#### P-06

# Anticoagulant therapy for acute venous thromboembolism during pregnancy: case-control study of delivery and post-partum

<u>E. Le Moigne</u><sup>1</sup>\*, S. Georget<sup>1</sup>, M. Collet<sup>2</sup>, M. Jacquot<sup>3</sup>, C. Tromeur<sup>1</sup>, D. Mottier<sup>1</sup>, A. Delluc<sup>1</sup>

<sup>1</sup>EA 3878 and Department of Internal Medicine and Chest diseases; <sup>2</sup>Department of Gynaecology, Brest University Hospital, Brest, France; <sup>3</sup>Department of Gynaecology, Centre Hospitalier Intercommunal de Cornouaille, Quimper, France

\*E-mail: emmanuelle.lemoigne@chu-brest.fr

**Object:** Anticoagulation during pregnancy is challenging because of the potential for maternal complications. We aimed to describe management of anticoagulation for the treatment of acute venous thromboembolism (VTE) during pregnancy and to compare delivery and post-partum outcomes in pregnant women with or without anticoagulant therapy.

**Method:** We studied clinical characteristics of all women included between 1992 and 2012 in the EDITH study for pregnancy-associated VTE. For each case, two controls were retrospectively matched for age, date and place of delivery.

**Results:** We included 31 women with acute VTE during pregnancy (24 with deep vein thrombosis and 7 with pulmonary embolism). Weight adjusted-dose subcutaneous low-molecular-weight-heparin was used for initial treatment in 71% of cases. Management of anticoagulation in peripartum was documented for 23 women: for 18, (78.3%), anticoagulation was held at least 24 hours prior to delivery.

We observed no recurrence of VTE and 9 bleeding events (4 before delivery, 1 early post-partum hemorrhage, 4 after discharge).

When compared to controls, women receiving anticoagulation had less obstetrical anaesthesia (66.7% versus 93.3% p=0.002), longer hospitalisation after delivery ( $6.93\pm2.23$  days versus  $5.60\pm1.56$  days, p=0.002) and lower breastfeeding rate (40% versus 68.9%, p=0.013).

**Conclusions:** Management of peripartum in women receiving anticoagulation for acute VTE during pregnancy was not in line with evidence-based clinical practice guidelines and should better be considered by a multidisciplinary team. We observed unexpected late postpartum bleedings when resuming oral anticoagulants. Ultrasound control of uterine vacuity before discharge could be useful for bleeding prevention.

#### P-07

## Midwife and obstetric doctors' views of venous thromboembolism (VTE) in the puerperium

<u>B. Guimicheva</u><sup>1\*</sup>, L.N. Roberts<sup>1</sup>, J.P. Patel<sup>1</sup>, D. Subramanian<sup>2</sup>, R. Arya<sup>1</sup> <sup>1</sup>Department of Thrombosis and Haemostasis, King's College Hospital NHS Foundation Trust, London, UK; <sup>2</sup>Department of Obstetrics and Gynaecology, King's College Hospital NHS Foundation Trust, London, UK \*E-mail: Boriana.guimicheva@nhs.net

**Aim:** To evaluate the views of midwives and obstetricians regarding VTE prevention for women during the puerperium.

It is well accepted that women identified at risk of VTE in the puerperium should be offered appropriate thromboprophylaxis through pharmacological and mechanical means. However it has been shown that only one-third of patients are appropriately risk assessed and given the appropriate level of thromboprophylaxis, with adherence during the postnatal period reported as sub-optimal [1–3]. Views of front-line midwives and obstetricians regarding VTE risk assessment and thromboprophylaxis are therefore of interest, as addressing misconceptions might improve risk assessment rates and implementation.

**Methods:** An online questionnaire was emailed to all clinical staff at King's College Hospital Maternity Unit; 137 responses were received (95 midwives and 40 doctors) between March 2013 and July 2014.

**Results:** 85.1% were involved in prescription/administration of thromboprophylaxis, with 99% basing decisions for use on the presence of VTE risk factors. Intermittent pneumatic compression, antiembolism stockings (AES) and anticoagulants were considered effective by 93.5, 85.2 and 100%. Doctors' and midwives had similar attitudes towards thromboprophylaxis, although fewer midwives believed AES were effective (80.0 vs 94.7% of doctors). Staff believed that continued adherence to thromboprophylaxis was low post discharge, estimating only 26% and 65% of women continued with AES and anticoagulant prophylaxis respectively. Download English Version:

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