07AP03-4
NAPaR: European non-interventional Post-Authorisation Safety Study of pattern of use and safety of Nordic Aprotinin.

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Background and Goal of Study: Aprotinin (AP) is a proteinase inhibitor drug. Initially introduced into clinical practice for the treatment of hyperfibrinolitic conditions, it was later used to reduce perioperative blood loss and transfusion needs. Preliminary data from the BART study suggesting an increased mortality in APtreated patients, led to its marketing withdrawal in 2008. In 2012, the European Medicine Agency revisited the totality of AP data and concluded that AP still has a place in preventing blood loss in patients undergoing isolated coronary artery bypass graft (iCABG) who are at high risk of major blood loss. As a condition to the reinstatement of AP's marketing authorisation, the Nordic Aprotinin Patient Registry (NAPaR, EUPAS11384) has been established, with AP distribution restricted to centres that perform cardiac surgery on cardio-pulmonary bypass and commit to participate in the Registry. NAPaR main objectives are to record information on the use of AP in Europe and to measure incidence of selected adverse events (death, thromboembolic event, renal dysfunction, anaphylaxy) and effectiveness of risk minimisation measures (anticoagulation monitoring, AP's test dose). Preliminary data on mortality rates are described.
Materials and Methods: Following AP relaunching, all patients exposed to AP must be entered in the NAPaR. Data are to be collected for at least 3 years or after inclusion of 12000 patients and upon Pharmacovigilance Risk Assessment Committee decision. Every 6 months, a Data and Safety Monitoring Committee (DSMC) reviews the data and advices Nordic whether or not it is recommended to continue the NAPaR.
Results and Discussion: The first patient was entered in the NAPaR in Feb-2016. Up to Jul-2018, 1419 adult patients have been treated with AP: 1175 (82.8%) from UK, 148 (10.4%) from Germany, 91 (6.4%) from Sweden, 3 (0.2%) from Austria and 2 (0.1%) from Finland. Only 3/314 patients treated on-label died, leading to an in-hospital mortality rate of 0.96%.
Conclusions: No safety signals compromising the completion of the study have been identified by the DSMC. The overall mortality rate is in line (or even better) with studies without AP.[1,2]
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2. Wang X, *et al. Ann Thorac Surg* 2010; **89**:1489–1495
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07AP03-5
Rotational thromboelastometry-guided management of congenital factor VII deficiency during an elective endovascular aortic aneurysm repair

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Background: Factor VII Padua is a type 2 variant congenital factor VII deficiency. We discuss the management conundrum in reduction of blood loss versus achieving anticoagulation during endovascular surgery in such a patient.
Case Report: We report a case of a 59 year old man with Factor VII Padua, planned for endovascular aortic aneurysm repair for a penetrating aortic ulcer. Rotational thromboelastometry (ROTEM) was used to guide the management of bleeding risk whilst maintaining anticoagulation during graft deployment. His baseline EXTEM showed an isolated prolonged clotting time (CT) as expected of his condition. 1.5mg of recombinant factor VIIa (Novoseven) was given 4 hours prior to surgery. EXTEM performed 42 minutes post NovoSeven administration showed a normalization of CT without further top-up doses, allowing surgical incision to proceed. Serial EXTEMs showed that further doses of Novoseven were not required. Heparin was omitted due to its unpredictable profile in factor VII deficiency.The patient was discharged 3 days after an uneventful procedure with minimal blood loss.
Discussion: Prothrombin time(PT)/International Normalized Ratio is conventionally used to guide NovoSeven dosing, but it has a long laboratory turnover. Conversely, ROTEM's fast result turnover time allows for rapid decision-making and guidance of further doses of NovoSeven, and is especially useful if there is significant bleeding. In particular, the EXTEM uses tissue factor as an activator, providing information on the extrinsic pathway factor activity similar to the PT. Also, ROTEM depicts the whole clotting process and can be used to rule out other causes of bleeding and identify hypercoagulability[1]. It allowed us to tread a fine line between maintaining a normal coagulation profile in view of arterial cannulation and a slightly anti-coagulated state during the stent deployment. We do not want to tip the patient into a prothrombotic state by over-dosing NovoSeven.
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Learning points: ROTEM allows for quick monitoring of the patient's coagulation status to reduce bleeding during femoral access, while achieving an anticoagulated state desirable for graft deployment. Further studies can evaluate its effectiveness in assessing post-operative hypercoagulopathic complications.

07AP03-6
Total aortic arch replacement with frozen elephant trunk (THORAFLEX™ HYBRID GRAFT): complications and transfusion

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Background and goal of study: Aortic dissecton type 1 is associated with high perioperative complications and a significant operative mortality. Frozen Elephant Trunk (FET) technique is one of the latest to be introduced to treat extensive and complex lesions of the thoracic aorta, including the descendent portion. FET (Thoraflex™ hybrid graft) allows to treat aortic arch and descending thoracic lesions in one-time surgery with promising results. The goal of this study is to compare complications and transfusion rates in pacients with Thoraflex™ hybrid graft in our hospital and those from national and international registries.
Materials and Methods: We retrospectively studied 10 patients who underwent total aortic arch replacement with Thoraflex™ hybrid graft between 2016 and 2018 in Puerta de Hierro Hospital. We considered intraoperative extracorporeal data, transfusion rates, perioperative complications and one month mortality. Statistical analysis was performed using SPSS.
Results and Discussion: There were no differences in intraoperative data and transfusion rates. Respiratory complications were significantly higher in our group. 30% of the patients developed tracheobronchial compression by the aortic false lumen, wich increase significantly ICU stay. Paraplegia appeared in only one patient (10%) as a late complication (45 days before surgery) by an embolic event.
Conclusions: Tracheobronchial compression by the aortic false lumen was an important complication in postoperative total aortic arch replacement with Thoraflex™ hybrid graft.
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07AP03-7
Chest cavity fire during emergency cardiac surgery: A case report and review of the literature

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Background: Operating room fires are a rare but potentially catastrophic occurrence[1].We report a case of a chest cavity fire associated with an air leak due to a ruptured bulla.
Case Report: A 60-year-old man presented for emergency repair of a type A aortic dissection. Past medical history was significant for chronic obstructive pulmonary disease and coronary artery bypass grafting one year prior. After induction, general anesthesia was maintained with inhaled sevoflurane (MAC 1) and intravenous propofol infusion (150 mg/hr). Surgery proceeded to sternotomy. At this point his right lung was noted to be adherent to the overlying sternum with prominent bullae. Despite careful dissection one of these bullae was punctured during sternotomy causing a significant air leak. In order to compensate for this the flows on the anesthetic machine were increased to 10 liters per minute and the proportion of inspired oxygen increased to 100%. Such was the extent of the leak that there were comments by the surgical team about the smell of sevoflurane. Shortly after this a dry pack in the presence of diathermy caught fire. This was immediately