## Spinal epidural haematoma following rivaroxaban administration after total knee replacement

Sir,

The incidence of neurologic dysfunction resulting from haemorrhagic complications following neuraxial blockade is estimated to be <1 in 150,000 epidurals, and 1 in 220,000 spinal anaesthetics. [1] The first reported case of epidural haematoma following rivaroxaban was published in 2014. [2]

A 59-year-old lady was admitted for elective right total knee replacement. She was a known case of hypertension, hypothyroidism, and congenital heart block (with indwelling cardiac pacemaker), on olmesartan and levothyroxine. Her pre-operative blood investigations including coagulation profile were normal. Combined spinal epidural anaesthesia was administered with a 20 gauge epidural catheter in L2-L3 epidural space and subarachnoid block with 23 gauge spinal needle in L3-L4 space with 3 ml of 0.5% bupivacaine. These procedures were atraumatic. A continuous epidural infusion of 0.125% bupivacaine at 3-5 ml/h was used for postoperative analgesia. The same night, the surgeon decided to prescribe rivaroxaban 10 mg for venous thromboembolism (VTE) prophylaxis instead of enoxaparin (which was routinely used) without informing anaesthesiologist. The anaesthesiologist ordered the removal of epidural catheter next day (i.e., 18 h after last dose of rivaroxaban). Second dose of rivaroxaban was repeated 6 h after catheter removal. Twelve hours after administration of a second dose, the patient developed severe back pain with new onset sensory and motor blockade along with bladder incontinence. As the patient had a cardiac pacemaker, an MRI was deferred. A computerised tomography was done which showed hypodense areas in L2-L3-L4 [Figure 1], a pre-emptive diagnosis of epidural haematoma was made. The patient underwent an emergency decompressive laminectomy, and the operative findings were blood clots in the L2-L-3-L4 epidural spaces extending into the spinal canal [Figure 2]. On the next day, she regained her bladder sensations and was discharged on post-operative day 5 with complete return of sensory and motor functions.

A number of novel oral anticoagulants that directly target factor Xa or thrombin have been developed in recent years. Among these, rivaroxaban is licensed for the prevention of VTE in patients undergoing elective hip or knee arthroplasty. Rivaroxaban was evaluated in phase III studies of the Regulation of Coagulation in Orthopaedic Surgery to prevent deep vein thrombosis and pulmonary embolism program (RECORD) in patients undergoing elective total hip or knee arthroplasty. [3] This study compared rivaroxaban with enoxaparin 40 mg



Figure 1: Sagittal computerised tomography scan showing hypodense signals

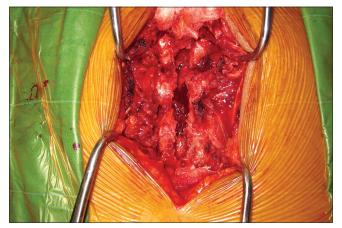


Figure 2: Intraoperative finding showing epidural haematoma

once daily (OD) or 30 mg twice daily (BID). Rivaroxaban was given at a fixed dose of 10 mg OD, and the first dose was administered 6 h post-operatively. Based on the outcomes of the RECORD studies, Rivaroxaban was approved for the prevention of VTE after elective hip or knee arthroplasty. No intra-spinal bleeding events were attributed to rivaroxaban administration in phase II or phase III prospective studies of rivaroxaban use after hip and knee arthroplasty. [4]

In our patient, the epidural catheter was removed 18 h after the last dose of rivaroxaban. A second dose was repeated 6 h after catheter removal. As per manufacturer's recommendation, 'an epidural catheter should not be removed earlier than 18 h after the last administration of rivaroxaban and next dose not to be administered earlier than 6 h after removal of the catheter.' Surgeon and anaesthesiologist are key players in the operating room, aiming for a common goal - safety and good surgical outcome of the patient. In this particular case, a pre-operative communication about the use of rivaroxaban would have made us opt for general anaesthesia with peripheral nerve blockade instead of neuraxial anaesthesia as the evidence for its safety is limited. The early surgical intervention resulted in complete recovery of our patient. This is in agreement with Vandermeulen et al., in whose series of 55 spinal haematomas, 38% patients had satisfactory neurologic recovery following surgical intervention within 8 h of onset of symptoms.<sup>[5]</sup>

We need to consider that adverse outcomes associated with concurrent use of neuraxial blockade and oral anticoagulants may be higher than those reported in clinical trials. Based on this experience, we recommend extreme caution in prescribing rivaroxaban to patients who have undergone neuraxial anaesthesia. Furthermore, we recommend that the time frame given by the manufacturer for drug administration needs reconsideration. More studies are required to prove the safety of rivaroxaban in the setting of neuraxial anaesthesia.

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