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Review

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Combined spinal epidural labour analgesia: Complications and their management

Nurullah Yilmaz^{a*}, Ismail Serhat Kocamanoglu^b, Hakan Abanoz^b

^a Department of Anesthesiology and Reanimation, Corum Training and Research Hospital, Corum, Turkey ^b Department of Anesthesiology and Reanimation, Faculty of Medicine, Ondokuz Mayis University, Samsun, Turkey

ARTICLE INFO		ABSTRACT Combined spinal-epidural analgesia (CSEA) is an effective and increasingly popular analgesia method used in vaginal delivery. CSEA provides rapid and excellent analgesia, allows mobilization, reduces drug consumption significantly and generally causes negligible maternal and fetal /neonatal adverse effects /complications not requiring treatment. The resulting adverse effects /complications are often associated with technical and /or agent/agents used and cause maternal and fetal /neonatal or, albeit rarely, serious adverse effects. Therefore, these cases should be monitored closely during analgesia, necessary preventive measures should be taken by anticipating the potential problems and if necessary, appropriate medical intervention should be performed.
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* Correspondence to: Nurullah Yilmaz Department of Anesthesiology and Reanimation, Corum Training and Research Hospital, Corum, Turkey e-mail: nurisbir117@hotmail.com		
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1. Introduction

Childbirth pain is one of the most severe types of pain which, a woman will experience in her lifetime. This experience may cause unnecessary suffering and creates physiological stress that can lead to undesirable effects on the mother and the fetus. Today, the idea that labour pain is acceptable or necessary is not adopted anymore and its presence is considered to be an indication for treatment (Sahin and Owen, 2006a). Neuraxial analgesia is currently considered to be the mostly preferred and most effective method for labour analgesia in developed countries. These techniques are extremely effective in pain relief, if performed in experienced hands using the correct technique and appropriate drug or drug combinations (Yilmaz, 2014). Among all neuraxial method, combined spinal-epidural analgesia (CSEA) is an ideal and increasingly popular analgesia technique for delivery. With its spinal components, CSEA provides rapid onset and safe and deep blockade. On the other hand, it allows the extension of blockade illimitable and variability of efficacy according to the need or desire with its epidural components (Cook, 2000; Hepner et al., 2000; Rawal et al., 2000; Gunaydin, 2012). Combined spinal epidural anesthesia offers the advantages of each method while minimizing their respective disadvantages. However, this method is technically more complicated than a single block application that may lead to additional complications and changes in current complications (Cook, 2000; Stamenkovic and Karanikolas, 2012).

Table 1. Combined spinal epidural labour analgesia related side effects and complications			
Technique-related	Drug-related		
Failure of the epidural component	Hypotension		
Failure of the spinal component	Nausea		
Migration of epidural catheter into the subarachnoid space	Vomiting		
Subarachnoid spread of epidurally administered drug	Itching		
Needle breakage or catheter disconnection	High neural blockade		
Complications of needle-through-needle technique	Respiratory depression		
Post-dural puncture headache	Cardiac arrest		
Postpartum low back pain	Uterine hyperstimulation/fetal bradycardia		
Postpartum neuraxial infection	Urinary retention		
Epidural abscess	Drop in body temperature and shivering		
Epidural, spinal or subdural hematoma			
Neurologic damage			

To achieve maximum benefit from neuraxial blocks and to minimize the complications, practitioners should have adequate anatomical and technical knowledge and particular experience and skills. This is a prerequisite for a successful and safe block. Additionally, practitioner should also be aware of the physiological effects of these blocks, the complications that may arise during the procedure and their measures and pharmacodynamics and pharmacokinetics of the agent used (Uzun and Reisli, 2013). Side effects and complications that may occur during CSEA administrations are dealt with in two main categories namely technique-related and drug-related complications (Sahin and Owen, 2006a; Uzun and Reisli, 2013) (Table 1).

- 2. Technique-related complications
- I- Failure of the epidural component
- a. Failure to identify the epidural space
- b. Delays in completing the epidural catheter placement

After administering the spinal dose, delays in the placement and maintenance of the epidural catheter may occur. This delay is usually short-term and insignificant but may change the features of block and may result in inability to achieve the labour analgesia (T10 level) targeted in the first stage of delivery. However, in this case, the epidural catheter can be used to complement the block.

- c. Failure to replace epidural catheter
- d. Misplacement of epidural catheter

In cases when dura is punctured via an epidural needle or catheter, high or total spinal block or subdural block that may lead to serious complications in the region where the catheter is placed (subarachnoid or subdural) may occur (Sahin and Owen, 2006b; Morgan et al., 2008). Since high-dose drug is used during epidural block, accidental spinal or subdural injections may cause similar clinical signs and symptoms. However, subdural outcomes are more serious and the emergence of these results may be delayed up to 15-30 minutes. In both cases, supportive treatment (intubation, mechanical ventilation, fluid and vasopressor support) should be applied. If accidental intraspinal administration of high dose is noticed, subarachnoid lavage should be performed and preservative-free normal saline should be administered by aspirating 5 ml of cerebrospinal fluid (CSF) several times.

Similarly, with the intravascular placement of epidural catheter and consequently intravascular administration of solution prepared for the epidural block, agents in the blood reaches its high levels and signs of toxicity may arise especially in central nervous system, cardio-vascular system and many other systems. In this case, along with anticonvulsant treatments supporting the vital functions, intravenous 20% lipid emulsion which is particularly effective in fatsoluble local anesthetics (LA) such as bupivacaine should be administered. For the prevention of incorrect placement of epidural catheter, doing careful aspiration of the catheter before each injection, the use of test dose and administration of agents in divided doses is extremely important (Morgan et al., 2008).

II- Failure of the spinal component

Since the distance between the tip of the epidural needle and spinal space ranges between 0.3 and 1 cm in the midline, especially during the spinal drug injection, spinal and epidural needles should be kept simultaneously and stably. The latest needle designs allow advancing of spinal needle (12-15 mm) from the tip of the spinal Tuohy needle. However, the use of long needles may pose handling and placement depth problems (Birnbach and Ojea, 2002). Lack of attention to the technical details during the application, poor sensation of dural puncture due to the use of fine needle and failure in monitoring CSF flux are the primary indicators of failure (Uzun and Reisli, 2013). After confirming that the epidural needle is in the epidural space, failure in monitoring CSF flux through spinal needle which is progressing towards subarachnoid space is the indication for short spinal needle or pushing the dura forward (tenting) (Birnbach and Ojea, 2002; Uzun and Reisli, 2013). Especially, pencil point (Whitacre, the Sprot) spinal needles do not perforate the dura. In this case, rotating the spinal needle to perforate the dura via a blunt needle, or repeating the procedure by changing the direction of the epidural needle may be useful. Failure in monitoring the CSF flux (flow) may be due to errors in the identification of the epidural space or blockage of spinal needle aperture with connective tissues (Uzun and Reisli, 2013).

Moreover, backward CSF flux and resistance to injection due to the use of fine spinal needles, deviation of the spinal needle from the midline and resistance loss of epidural space can be mistaken with CSF and this may lead to failure of spinal component (Stamenkovic and Karanikolas, 2012).

III- Migration of epidural catheter into the subarachnoid space or complications related to the intrathecal route of drug administration

a. Migration of epidural catheter into the subarachnoid space

Although rare, needle-through- needle technique may lead to this complication. This problem can be eliminated using a separate needle and aperture technique as in the back-hole epidural needle. During CSEA, subarachnoid placement of the epidural catheter is more common than the migration. This generally occurs in cases when dural puncture is not felt due to the use of small gauge epidural needle. Studies have shown that it is not possible for epidural catheter to pass into the subarachnoid space following perforation of the dura through a small gauge spinal needle and that performing more than one dural puncture increases the risk for migration (Birnbach and Ojea, 2002). Drugs given through epidural catheter migrated to subarachnoid space may lead to high or total spinal block (Sahin and Owen, 2006b; Uzun and Reisli 2013).

b. Subarachnoid spread of epidurally administered drug Determining a higher level of dermatomal blockade than expected with a single dose administration of LA following CSEA indicates subarachnoid flux of epidural drug. However, unless the dura is not perforated via epidural needle during labour analgesia administration or large volumes of bolus volumes are not given, this flux is clinically insignificant. Epidural drugs can also reach spinal space as a result of intrathecal migration of the catheter. However, this flux does not cause any clinically significant complications (Birnbach and Ojea, 2002). This is more common in cases where dura is perforated accidentally with a Tuohy needle and this may increase the incidence of complications such as high block, total block, or respiratory depression (Uzun and Reisli, 2013). Therefore, all epidural doses should be administered incrementally and the patients receiving continuous epidural infusion should be monitored in every hour in terms of sensory and motor block (Birnbach and Ojea, 2002).

IV- Needle breakage or catheter disconnection

Needle breakage or catheter disconnection is quite rare. Broken needle tip can be removed to prevent tissue damage. Unless the broken catheter tip does not give symptom, removal is not recommended. When the epidural catheter is excessively advanced, it may get tangled and looped. In fact, most of these catheters can be removed slowly and constant withdrawal (Sahin and Owen, 2006b).

V- Complications of needle-through-needle technique

Theoretically, friction, damage or breakages of metallic particles due to abrasion between spinal and epidural needles are possible complications. However, these complications have not been yet clinically proven. Microscopic and atomic absorption spectroscopy techniques can not verify the presence of metal particles after passing the 29 gauge Quincke needle through Tuohy 18 gauge needle (five times) (Birnbach and Ojea, 2002).

VI- Post-dural puncture headache

Post-dural puncture headache (PDPH) occurs as a result of leakage of CSF which leads to traction of pain sensitive structures such as meninges, cranial nerves, bridging veins and tentorium following the puncture of duramater intentionally or accidentally during neuraxial intervention. Similarly, by perforating the dura, epidural catheter can also cause PDPH at any time. Headache may also develop in

acute leakage of CSF even at small volumes. CSF leakage and PDPH incidence are directly proportional to the size of hole left in the dura. The size of the puncture in the dura is associated with the caliber and the type of needle or catheter. The incidence of PDPH is low with fine or pencil point spinal needle. However, the use of sharp point needle with tip of the needle parallel to longitudinal axis (caudad or cephalad) reduce the size of the dural puncture and thus the incidence of PDPH. Especially young age, female gender and pregnancy increase the probability of PDPH. It usually occurs 12-72 hours following dural puncture but may also develop earlier. The most common symptoms include sudden onset of headache, neck pain, and cranial nerve symptoms (alteration in vision or hearing). The pain developing out of spreads to frontal region through trigeminal nerve. On the other hand, the pain developing out of lower tentorium may spread to occipital region and the neck through the vagus and upper cervical nerves. The headache can be frontal or round extending to the neck and often throbbing, continuous and severe. It is always associated with body position. While standing or sitting, the pain exacerbates but lying position reduces or terminates the pain. It is rarely accompanied by nausea and vomiting. Other uncommon symptoms include dizziness, tinnitus, hearing loss, photophobia, diplopia and neck stiffness. PDPH usually resolves spontaneously in a few days to one week for most patients. However, in some untreated cases, it persists for several weeks, months or years or even requires surgery. To prevent PDPH, fine-point needles should be used and intervention should be performed in parallel with dural fibers. Psychological support should be provided to the patients by informing them that the case is not vital or will resolve after a time, bed rest should also be recommended, oral or intravenous fluid support should be provided, stool softeners and soft diets for prevention of valsalva maneuver should be initiated and analgesics (acetaminophen, NSAIDs) and some cerebral vasoconstrictor such as caffeine should be given. If such approaches fail, 15-20 ml autologous blood or 20-30 ml low molecular weight dextran (dextran 40) or epidural patch gelatin may be administered at puncture level or lower space. Epidural blood patch provides tamponade and mass effect to the puncture region and allows CSF movement to the cephalad. Today, PDPH rarely requires epidural patch thanks to newly designed epidural needles. It has been reported that administration of epidural blood patch within the first 24 hours increases the success of the treatment. In addition, epidural saline bolus or infusion and theophylline, derivative of methylxanthine and serotonin agonists offer unique benefits to the treatment (Sahin and Owen, 2006b; Morgan et al., 2008).

VII- Postpartum low back pain

Low back pain is a common symptom in the general population and especially in pregnant women regardless regional interventions are performed or not. It was reported in prospective studies that neuraxial analgesia does not affect the incidence of low back pain (Sahin and Owen, 2006b). However, especially, while advancing the epidural needle during the procedure, tissue damage may occur in the skin and subcutaneous tissues, muscle and ligaments. Localized or inflammatory response accompanied by reflex muscle spasms due to tissue damage is considered to be responsible for the pain (Kuczkowski and Chandra, 2008). Physiological and anatomical changes during pregnancy (particularly, increase in lumbar lordosis and stress on the sacroiliac joints) are predisposing factors for low back pain. Depending on the compression of lumbosacral nerves, low back pain accompanied by radicular symptoms may also develop. Hematoma in the supraspinous ligament can also cause low back pain. It usually lasts for 24-48 hours or sometimes several months. Doing physical exercise and maintaining proper posture are essential for the prevention of chronic low back pain (Sahin and Owen, 2006b). Analgesics, hot or cold application and physical therapy may be sufficient in the treatment (Sahin and Owen, 2006b; Morgan et al., 2008).

VIII- Postpartum neuraxial infection

As long as asepsis rules are followed, serious infections associated with neuraxial blocks rarely occur (Sahin and Owen, 2006b). In comparison to the conventional epidural or single dose spinal anesthesia, the risk for developing infectious complications has been shown to increase in CSEA, a more invasive technique (Miro et al., 2008; Uzun and Reisli, 2013). The infection usually develops from the microorganisms entering the body through the skin during the procedure or the contamination of the materials used in solutions injected to the patients (Morgan et al., 2008). Infection may also develop during injections following epidural catheter. Therefore, mask should be worn, epidural catheter tip should be kept closed and only sterile solutions should be injected. It usually manifests itself in the form of bacterial or aseptic meningitis. Bacterial meningitis is often characterized by fever, headache, pain and stiffness of the neck and increase in polymorphonuclear white blood cells in CSF, decrease in glucose levels, increase in protein level and gram staining following neuraxial block. Aseptic meningitis is similar to bacterial meningitis but no microorganism is present in CSF. It probably develops from chemical irritation of the spinal cord and meninges. Symptoms usually occur within 6-24 hours after neuraxial block in the form of fever, headache, neck stiffness and photophobia. Lymphocytosis and white cell proliferation, normal glucose and protein increase are observed in CSF analysis. Gram staining does not detect the bacteria (Sahin and Owen, 2006b).

IX- Epidural abscess

Epidural abscess is a rare but serious complication of neuraxial block (mostly epidural catheter) that should be immediately diagnosed and treated. It becomes symptomatic within the few days/weeks following the intervention. Fever, fatigue, headache and pain in the abscess site are typical symptoms. Nerve root pain or radicular pain develops within 1-3 days following the onset of the epidural abscess. As the abscess enlarges, neurological deficit (pain and weakness in the lower extremities, bowel and bladder dysfunction, and paraplegia) due to compression on spinal cord and the blood vessels feeding the spinal cord are observed. The prognosis highly correlates with the degree of neurological dysfunction. Culture samples should be taken from catheter tip, blood and, if any, infection site. Treatment with antibiotics and percutaneous drainage may not be sufficient. Particularly, if neurological symptoms develop, early neurosurgical consultation should be requested and decompression with

laminectomy may be required within the 6-12 hours (Sahin and Owen, 2006b; Morgan et al., 2008).

X- Epidural, spinal or subdural hematoma

Needle or catheter trauma to epidural veins frequently results in benign, self-limiting, minor bleeding in the spinal canal. Although quite rare, significant hematoma may occur in the presence of coagulation or bleeding disorders. The clinical picture is similar to epidural abscess due to the reasons such as pathological effects on the spinal cord and nerves, compression of mass effect to the nerve tissue, direct pressure damage or ischemia. However, unlike epidural abscess, symptoms appear instantaneously. If hematoma is suspected, neuroimaging (CT, MRI or myelography) should be performed and neurosurgery consultation should be requested immediately. Neurological recovery is possible if the surgical decompression is performed within 8-12 hours (Morgan et al., 2008). Subdural hematoma following dural puncture is also rare. In this case, non-position related persistent headache, nausea and /or vomiting, confusion and mental status changes can occur. Focal neurological signs may also develop. The diagnosis is established via computed tomography or Magnetic resonance imaging. Surgical drainage is the first choice of treatment (Sahin and Owen, 2006b).

XI- Neurologic damage

Spinal cord or nerve roots may be damaged as a result of neuraxial interventions (Sahin and Owen, 2006b; Morgan et al., 2008). Primarily, this damage is attributed to the trauma occurring in the nerve or vascular structures caused by needle or catheter, LA-induced neurotoxicity and the infection (Sahin and Owen, 2006b). Technically, attempting several interventions in a difficult block is an important risk factor. Although most of the neurological deficits improve spontaneously, some can be permanent. Especially, paresthesia associated with needle or catheter or pain during injection is the sign for nerve damage. If the patient complaints about paresthesia, needle position should be changed. If paresthesia is accompanied by pain, the procedure should be terminated immediately by withdrawing the needle (Morgan et al., 2008). After administering spinal dose, the presence of paresthesia cannot be detected in applications in which the needle and the catheter are inserted. Because epidural needle is inserted before administering the spinal dose, this problem is not experienced in needle-through-needle technique (Birnbach and Ojea, 2002). Paraplegia develops if the analgesia is directly injected into the spinal cord. When the damage occurs in the region of the conus medullaris, paralysis in the biceps femoris muscle and anesthesia and isolated sacral dysfunction may develop in the posterior thighs, anal area and big toe. Even demyelination may be observed in the nerve tissue (Morgan et al., 2008). Neurological damage can be prevented by showing attention towards technical rules, anatomical distance measurement, position and sensation of the anatomical layers during the intervention, paresthesia and needle insertion (Yilmazlar, 2012). The treatment of neurological deficits is damage-specific. If any, deficits should be consulted with a neurologist. Steroids are commonly used to reduce swelling and inflammation. Physical therapy may be appropriate in medium and long-term neurological deficits (Sahin and Owen, 2006b).

Drug-related complications 1- Hypotension

Maternal hypotension is the most common drug-induced complication occurring in obstetric neuraxial techniques (Sahin and Owen, 2006b). However, there are also studies indicating that the incidence of hypotension in CSEA is less than that of in single epidural or single spinal block (Uzun and Reisli, 2013). If necessary measures are not taken or it is not treated properly, maternal hypotension can be fatal for the mother and the baby. While moderate hypotension does not lead to significant maternal symptoms, it may not be tolerated by the fetus in the same way. Here, the important matter is that in what proportion the decrease in maternal blood pressure will reduce the uterine blood flow. Episodes of hypotension lasting for more than four minutes may cause acidotic neonatals with low Apgar scores. Compared to nonpregnant women, hypotension due to neuraxial analgesiainduced sympathetic block in can develop more rapidly in pregnant women and compensation of intrinsic homeostatic mechanisms and therefore hypotension may become much more difficult. Moreover, pregnant women are inclined to hypotension due to the conditions such as aortocaval compression, uterine contractions and lack of fetal head engagement (Sahin and Owen, 2006b). Sympathectomy with its vasodilation leads to reduction in cardiac preload and end-diastolic volume index and stroke index but increases in heart rate. However, these attacks induced by neuraxial drugs are predominantly temporary and easily prevented or treated (Birnbach and Ojea, 2002). Turning the patients to left lateral position that ensures uterus deviation to the left in order to eliminate aortocaval compression and intravenous hydration administration with dextrose-free fluids are highly effective methods to prevent maternal hypotension. When maternal hypotension develops, the intermittent intravenous administration of vasopressors such as ephedrine 5-10 mg or phenylephrine 50-100 μ g can provide an effective treatment. However, the treatment should be started in time to obtain good neonatal outcomes. Since the first sign of hypotension can be nausea and vomiting due to cerebral hypoperfusion, these types of findings and alterations in fetal heart rate may guide the treatment (Sahin and Owen, 2006b).

2- Nausea and vomiting

Although these complications are relatively common after neuraxial blocks administered for caesarean section, they are not frequent after CSEA. Possible cause of nausea and vomiting after neuraxial blocks in obstetric patients include central opioid use, sympathetic blockade-induced hypotension and cerebral hypoperfusion due to hypotension, and peritoneal or visceral traction. Opioid-induced nausea and vomiting occur as a result of stimulation of the chemoreceptor trigger zone in the floor of the fourth ventricle. Intravenous administration of 10 mg metoclopramide is used for the treatment. Selective serotonin type 3 receptor antagonists such as ondansetron and granisetron and subhypnotic-dose of propofol are used for the treatment of central block-induced nausea and vomiting in cesarean section. On the other hand, there is no study showing the efficacy of these drugs in the treatment of central block-induced nausea and vomiting in spontaneous delivery (Birnbach and Ojea, 2002; Sahin and Owen, 2006b).

3- Itching

Itching is the most common side effects of intrathecal opioid use for labour analgesia, but almost no antipruritic treatment is needed following fentanyl and sufentanyl. Although the exact cause of opioid-induced itching in CSEA is unknown, response of neurons in the superficial laminae of the spinal dorsal horn to histamine and other irritants is estimated to be involved in the itching sensation signals. Selection of spinal adjuvant may affect the incidence of itching. It was reported that administration of intrathecal bupivacaine 2.5 mg plus 25 μ g fentanyl to labouring women leads to reduction in the incidence of itching in all parts of the body, except for the face. Recently, spread of opioids and thus control of itching is attempted by adding dextrose to spinal opioid drugs. Antihistamines, opioid antagonists and subhypnotic-dose propofol can be used in the treatment (Birnbach and Ojea, 2002).

4- High neural blockade

Administration of excessive doses in neuraxial blocks, not reducing doses in specific patient groups (elderly, pregnant women, obese or very short individuals), hypersensitivity to LA agent or propagation may increase the level of neural block. When the block reaches to the cervical level, hypotension, bradycardia and respiratory failure may develop. The patients complain of nausea before hypotension and / or they may vomit. In addition, they may experience power loss and numbness in the upper extremities. Clinical picture characterized by blackout, loss of consciousness, apnea, and hypotension that occurs as a result of increase in block level is called as 'high' or 'total blockade'. In this case, supportive treatment (ventilatory support, ensuring adequate ventilation, circulation support) should be initiated immediately (Morgan et al., 2008).

5- Respiratory depression

Intrathecal fentanyl and sufentanyl affect the respiratory center in the brain stem and severe respiratory depression or respiratory arrest may occur. The patient is turned to the left and respiratory support is provided with %100 O_2 and 0.4-0.8 mg intravenous naloxone is given, and if necessary, the patient is intubated (Sahin and Owen, 2006b).

6- Cardiac arrest

During neuraxial blocks, conditions often starting with bradycardia and resulting in cardiac arrest may develop. Prophylactic volume expansion therapy and early and aggressive vagolytic (atropine) treatment of bradycardia and subsequently, if necessary, administration of ephedrine and epinephrine are useful for the prevention of cardiac arrest (Morgan et al., 2008).

7- Uterine hyperstimulation / fetal bradycardia

Possibly due to the decrease in maternal catecholamines, spinal opioids may accelerate uterine hypertonicity which can cause placental hypoperfusion and fetal bradycardia. This can pose a problem during the stimulation of oxytocin which increases uterine activity. The previous studies showed that fetal heart rate abnormalities at high rates are closely associated with high-dose intrathecal opioid use. More importantly, it was observed that none of fetal heart rate variations identified at lower doses does not require immediate delivery and that all the variations are temporary and disappear within 30 minutes. In addition, no significant difference was observed between pregnant women to whom analgesia was achieved via systemic medication or non-pharmacological methods and those undergoing CSEA, excluding obstetric factors, in terms of emergency cesarean incidence. Although it is not a complicated medical condition, the researchers recommend continuous fetal monitoring within the first 40-60 minutes after administration of labour analgesia (Birnbach and Ojea, 2002). When fetal heart rythm abnormalities are detected, treatment options should include the following interventions: discontinuation of oxytocin infusion, providing oxygen support, turning the patients to the left side or controlling the uterine contractions via abdominal palpation by using kneeelbow position, controlling blood pressure and, if needed, administering intravenous fluid and ephedrine support and if uterine hypertonicity is present, administering terbutaline or nitroglycerin (Sahin and Owen, 2006b).

8- Urinary retention

Urinary retention may occur due to lumbar and sacral (S2-4) nerve root involvement in the neuraxial blocks. The resulting symphatic block causes relaxation of sphincters and increase

in intraluminal pressure with vagal tone dominance. Giving plentiful fluid in an attempt to prevent or to treat hypotension may also cause urinary retention. Therefore, emptying the bladder before the procedure, avoiding unnecessary and excessive fluid infusion in cases in which catheter is not inserted and massaging the bladder at intervals are needed (Kayhan, 2007; Yilmazlar, 2012).

9- Drop in body temperature and shivering

Vasodilation induced by sympathetic block may lead to redistribution of central heat to the periphery and thus temperature reduction of 1-2°C (a trend towards hypothermia). In addition to vasodilation, the effect of LAs absorbed from epidural space on heat-regulating centers and the direct effects of cold LAs on spinal cord may cause shivering (Kayhan, 2007).

3. Conclusion

The use of CSEA for labour analgesia is becoming widespread in the modern age. However, knowing the possible adverse effects /complications of this method and treating them most appropriately, when necessary, will minimize maternal and fetal /neonatal adverse effects.

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