Spinal anesthesia using hyperbaric prilocaine 2 % versus hyperbaric bupivacaine 0.5 % for day case surgery

B|BRAUN SHARING EXPERTISE

Etriki RGS, Abd Ellatif HK, Sayouh EF, Mohammed AMEgypt J Hosp Med 2022; 87(1):1658–65.

Objective

The study aimed to compare spinal anesthesia using hyperbaric prilocaine 2 % and hyperbaric bupivacaine 0.5 % for day case surgery.

Methods

Prospective, double-blind, randomized controlled trial. Patients scheduled for day case surgery received spinal anaesthesia with either

60 mg **prilocaine** 2 % or
15 mg hyperbaric **bupivacaine** 0.5 %

Results

Patient characteristics

	Prilocaine (n=33)	Bupivacaine (n=33)
Age (years)	35.1 ± 9.7	38.1 ± 13.1
BMI (kg/m²)	25.9 ± 1.0	25.1 ± 2.5
Gender (m/f)	14/19	17/16

values are mean ± standard deviation; BMI: body mass index

Block onset times

Onset time of sensory & motor blocks were significantly faster with prilocaine:

Sensory: 1.95 ± 0.36 vs. 2.80 ± 0.4 min (p<0.001)
Motor: 4.87 ± 0.7 vs. 6.1 ± 1.0 min (p<0.001)

Duration of blocks

Duration of sensory & motor blocks were significantly shorter with prilocaine:

Sensory: 92.4 ± 2.5 vs. 207.6 ± 10.9 min (p<0.001)
Motor: 110.7 ± 8.8 vs. 253.9 ± 19.8 min (p<0.001)

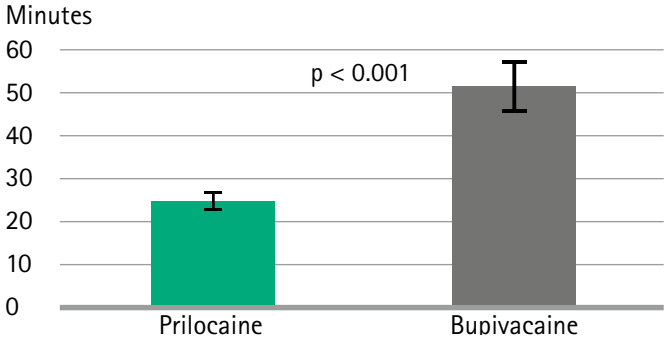
Time to voiding

Time to spontaneous voiding occurred more than 1 hour earlier with prilocaine:

256.4 ± 21.5 vs. 345.4 ± 24.5 min (p<0.001)

Time spent in PACU

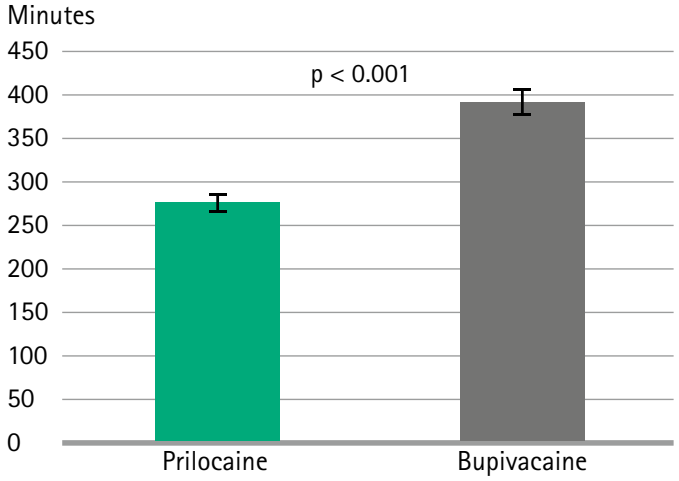
The time spent in the post anaesthesia care unit (PACU) was reduced by 50 % with prilocaine: 25 ± 2.5 vs. 50.9 ± 8.2 min (p<0.001)



values are mean +/- standard deviation

Time to discharge

Time until readiness to discharge home was almost 2 hours earlier with prilocaine:



values are mean +/- standard deviation

Haemodynamics

Heart rate and mean arterial blood pressure were not significantly different between prilocaine and bupivacaine.

Conclusion:

When used for spinal anaesthesia prilocaine is faster than bupivacaine in terms of onset and offset of sensory & motor blocks. With prilocaine patients require less time until voiding, less time in the PACU and patients can be discharged almost 2 hours earlier. With regard to haemodynamics prilocaine shows no disadvantages over bupivacaine.

Product Information

Name of the the medicinal product
Takipril 20 mg/ml solution for injection

Composition
1 ml of solution for injection contains 20 mg of prilocaine hydrochloride (equivalent to 2%) 1 ampoule with 5 ml solution, contains 100 mg of prilocaine hydrochloride

Excipients:
1 ml contains 0.0086 mg sodium.
Glucose anhydrousor glucose monohydrate, sodium hydroxide 1N (for pH adjustment), water for injection.

Therapeutic indications
Takipril is indicated in adults for spinal anaesthesia in short-term surgical procedures.

Contraindications
Takipril must not be used in patients wit hypersensitivity to prilocaine hydrochloride, other amide-type local anaesthetics or to any of the excipients; serious problems with cardiac conduction; severe anaemia; decompensated cardiac insufficiency; cardiogenic and hypovolemic shock; congenital or acquired methemoglobinemia; concomitant anticoagulant therapy general and specific contraindications for the technique of subarachnoid anaesthesia. The use of Takipril in children younger than 6 months is contraindicated due to a higher risk of developing methemoglobinemia. The intravascular injection of Takipril is contra-indicated. Takipril must not be injected into infected areas.

Undesirable effects
The possible undesirable effects due to the use of Takipril are generally similar to the undesirable effects of other local anaesthetics for spinal anaesthesia from the amide group. The undesirable effects induced by the medicinal product are difficult to distinguish from the physiological effects of the nerve block (e.g. reduction in arterial pressure, bradycardia, temporary urine retention), from direct effects (e.g. spinal hematoma) or the indirect effects (e.g. meningitis) of the injection or from the effects due to the loss of cerebrospinal liquid (e.g. post-spinal headache).

Undesirable effects are listed according to their frequencies as follows:
Very common: (≥ 1/10)
Common: (≥ 1/100 to < 1/10)
Uncommon: (≥ 1/1000 to < 1/100)
Rare: (≥ 1/10000 to < 1/1000)

The signs of intoxication from local anaesthetics are similar for any injected preparation, both in the way in which they manifest, and in their treatment.

System organ class
Blood and lymphatic system Disorders:
Rare: Methemoglobinemia, Cyanosis.

Immune system disorders:
Rare: Anaphylactic shock, anaphylactic reactions, allergic reactions, itching.

Nervous system disorders:
Common: Paresthesia, Dizziness.
Uncommon: Signs and symptoms of CNS toxicity (convulsions, circumoral paresthesia, loss of consciousness, shaking, feeling of numbness affecting the tongue, speech problems, hearing problems, tinnitus, visual problems).
Rare: Arachnoiditis, neuropathy, lesions of peripheral nerves.

Eye disorders:
Rare: Diplopia.

Cardiac disorders:
Uncommon: Bradycardia.
Rare: Cardiac arrest, arrhythmia.

Vascular disorders:
Very common: Hypotension.
Uncommon: Hypertension.
Respiratory, thoracic and mediastinal disorders:
Rare: Respiratory depression.
Musculoskeletal and connective tissue disorders:
Uncommon: Back pain, temporary muscle weakness.

Gastrointestinal disorders:
Very common: Nausea.
Common: Vomiting.

In spite of the demonstrated high clinical tolerability of Takipril, undesirable toxic effects cannot be excluded in the presence of plasma levels above a critical threshold. These undesirable effects mainly manifest as symptoms affecting the central nervous and cardiovascular system. The most effective prophylactic measures are scrupulous compliance with the recommended posology for Takipril, with it being essential for the doctor to check its action (visual and verbal contact with the patient), as well as careful aspiration prior to injecting the solution. Mild undesirable effects (feeling dizzy or dazed) can be attributed to moderate overdose and generally resolve rapidly after reducing the dose or halting administration of Takipril.

Serious undesirable effects are attributable to significant overdose and/or accidental injection of local anaesthetic into a blood vessel. They manifest as symptoms affecting the central nervous system (restlessness, speech problems, disorientation, dizziness, muscle contractions, cramps, vomiting, loss of consciousness, respiratory arrest and mydriasis) and the cardiocirculatory system (raised arterial pressure and pulse frequency, arrhythmia, drop in arterial pressure, asystole) following irritation and/or depression of the cerebral cortex and the cerebral marrow. In addition, following inhibition or block of the cardiac conduction system, cardiac frequency may slow down and myocardial depression may occur. Any problems relating to metabolism (liver) or excretion (kidney) of Takipril should also be considered as other possible causes of undesirable effects.

Warnings
Keep out of the sight and reach of children.

Directions for proper use:
5 ml ampoules of solution for injection are exclusively single-use. Any remaining product must be disposed of.

Note
Prescription only

Not all products are registered and approved for sale in all countries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

B. Braun Melsungen AG, 34212 Melsungen, Germany, 02/2020

B. Braun Melsungen AG | Hospital Care | 34209 Melsungen | Germany
Tel. +49 5661 71-0 | www.bbraun.com

Date of last revision: 05.2023