# Spinal anaesthesia with hyperbaric prilocaine in day-case perianal surgery: randomised controlled trial

B|BRAUN SHARING EXPERTISE

*Kaban OG, Yazicioglu D, Akkaya T, Sayin MM, Seker D, Gumus H. Sci World J 2014; 2014:608372.*

**Objective**

The study aimed to compare hyperbaric prilocaine and bupivacaine in terms of sensory block resolution and time to home readiness in day-case spinal anaesthesia.

**Methods**

Prospective, double-blind, randomized controlled trial in patients undergoing elective ambulatory perianal surgery under spinal anaesthesia with either

30 mg **prilocaine** 2%+ opioid or
7.5 mg hyperbaric **bupivacaine** 0.5% + opioid

**Results**

*Patient characteristics*

| | Prilocaine (n=25) | Bupivacaine (n=25) |
|---|---|---|
| Age (years) | 37.8 ± 12.4 | 38.4 ± 13.3 |
| BMI (kg/m²) | 26.4 ± 5.2 | 27.3 ± 5.2 |
| Gender (m/f) | 12/13 | 16/9 |

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

*Onset of Sensory Block*

Time to L1 block and time to maximum sensory block was faster with prilocaine:

**L1 block:** 4.6 ± 1.3 vs. 5.9 ± 1.9 min (p=0.017)

**Max. block:** 13.2 ± 7.5 vs. 15.3 ± 6.6 min (p=0.04)

*Maximum dermatomal spread*

Maximum dermatomal spread of the block was similar between both groups:

T9 (T6-T12) vs. T9 (T6-T12) (p=0.657)

*Resolution of sensory block*

Time of sensory block regression to L1 and to S3 was significantly shorter with prilocaine:

**L1:** 45.7 ± 21.9 vs. 59.7 ± 20.9 min (p=0.024)

**S3:** 133.8 ± 41.4 vs. 200.4 ± 64.8 min (p<0.001)

*Degree of Motor block*

The degree of motor block was similar at the time that each group reached maximum sensory block.

*Resolution of motor block*

After one hour significantly more patients in the prilocaine group had a complete regression of motor block:

88% vs. 44% (p<0.001)

*Pain scores*

Postoperative pain scores did not differ significantly between both groups.

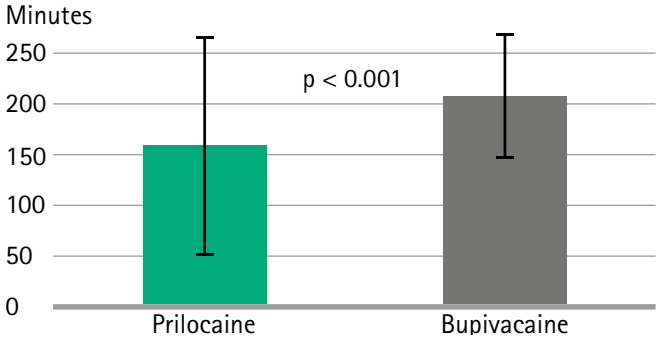
*Time spent in PACU*

Patients with prilocaine required less time in the post anaesthesia care unit (PACU)

63 ± 28 vs. 99 ± 37 min (p<0.001)

*Home readiness*

Home readiness was reached almost 1 hour earlier with **prilocaine:**




*values are mean +/- standard deviation*

**Summary:**

When used for spinal anaesthesia prilocaine is faster than bupivacaine in terms of onset and offset of sensory & motor blocks. The faster offset of the sensory block in the prilocaine group does not lead to higher postoperative pain scores.

The advantageous block regression profile of prilocaine allows patients to spend less time in the PACU and supports a faster patient discharge.

# 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