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EFFECT OF TOPICAL EMLA CREAM APPLICATION ON PAIN ATTENUATION PRIOR TO SPINAL ANESTHESIA IN SCHOOL-AGE CHILDREN UNDERGOING INFRAUMBILICAL SURGERY: A RANDOMIZED CONTROLLED TRIAL

Anaesthesiology

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ABSTRACT

Central neuraxial blockade, particularly spinal anesthesia, represents a cornerstone technique for infraumbilical surgical interventions in pediatric populations, offering advantages such as hemodynamic stability, cost-effectiveness, and rapid onset. However, procedural pain associated with spinal needle insertion often impedes patient cooperation, especially in school-age children (5-12 years), due to heightened apprehension and limited tolerance. This prospective, randomized, double-blinded, controlled trial evaluated the analgesic efficacy of topical eutectic mixture of local anesthetics (EMLA) cream (2.5% lidocaine and 2.5% prilocaine) applied 60-90 minutes prior to spinal anesthesia in 72 children undergoing elective infraumbilical surgery. Participants were allocated to either the study group (Group S, n=36; EMLA cream) or control group (Group P, n=36; placebo cream). Primary outcomes included pain assessment via Visual Analog Scale (VAS) and Behavioral Pain Scale (BPS) at needle insertion, alongside hemodynamic variations. Secondary outcomes encompassed the number of spinal attempts and adverse events. Results demonstrated significantly lower VAS (1.08 ± 1.02 vs. 3.11 ± 1.2; $p<0.001$) and BPS (2.0 ± 1.0 vs. 4.2 ± 1.1; $p<0.001$) scores in Group S. Hemodynamic perturbations, including heart rate elevations, were attenuated in Group S ($p<0.01$ at select intervals). Ketamine requirements were reduced (5 vs. 16 patients; total dose 1.2 ± 0.5 mg/kg vs. 3.5 ± 1.0 mg/kg; $p<0.01$), with fewer adverse effects ($p<0.05$). No significant difference in spinal attempts was observed (1.2 ± 0.5 vs. 1.6 ± 0.69; $p=0.8$). Topical EMLA cream effectively mitigates procedural pain, enhances cooperation, and exhibits a favorable safety profile, advocating its integration into pediatric anesthetic protocols for spinal anesthesia.

KEYWORDS

INTRODUCTION

Central neuraxial blockade, encompassing spinal anesthesia, constitutes a well-established, straightforward, and comparatively secure modality for providing anesthesia in surgical procedures below the umbilicus. This technique affords comprehensive sensory and motor blockade, thereby facilitating operative conditions conducive to surgical precision. The merits of spinal anesthesia are manifold: it is technically uncomplicated to administer, economically viable, preserves spontaneous ventilation, diminishes the risk of pulmonary aspiration, induces prompt anesthetic onset, and ensures profound muscular relaxation. Furthermore, it exhibits superior efficacy with minimal pharmacotherapeutic requirements. Notwithstanding these benefits, spinal anesthesia is not devoid of constraints and potential adverse sequelae, including a finite duration of effect, post-dural puncture headache, hypotensive episodes, and limited predictability in block height. These drawbacks are largely mitigatable through meticulous procedural execution, adherence to aseptic protocols, and judicious patient selection [1].

In pediatric cohorts, the adoption of spinal anesthesia for infraumbilical surgeries of delimited duration has witnessed progressive augmentation, attributable to enhanced hemodynamic constancy relative to adult counterparts [2]. Pediatric spinal anesthesia diverges from adult paradigms in several pharmacodynamic and anatomical dimensions, including the requisite dosage of local anesthetics, cerebrospinal fluid (CSF) volume and pressure dynamics, the degree of neural myelination, and vertebral column/spinal cord morphological variances.

Patient reticence toward spinal anesthesia predominantly stems from anticipatory anxiety regarding needle insertion pain, which poses a substantial impediment to efficacious administration, necessitating optimal patient collaboration and positioning to avert iterative needle punctures [3]. This challenge is amplified in pediatric patients, who exhibit diminished pain tolerance, elevated anxiety levels, procedural unfamiliarity, and suboptimal cooperation compared to adults [4]. Pain manifests as a consequence of nociceptive activation within the nervous system, triggered by nociceptor stimulation. This neural transduction propagates via the spinal cord to cerebral centers, conveying tissue damage intelligence sans conscious perception. The paramount objective of anesthesia is perioperative pain amelioration. Mitigating needle insertion pain substantially augments the efficiency, expediency, and feasibility of spinal anesthesia, while bolstering patient cooperation and satisfaction through anxiety alleviation [5]. Such mitigation may be accomplished via sedative pharmacotherapy, local infiltrative anesthesia, or topical local anesthetic application.

A plethora of local anesthetics have been employed topically, encompassing lidocaine, dibucaine, tetracaine, benzocaine, and amethocaine. Typically, these formulations yield efficacious yet ephemeral analgesia for invasive interventions. Preparations such as tetracaine gel and liposomal lidocaine have been harnessed for dermal anesthesia. Adjunctive physical modalities to augment transdermal drug delivery include iontophoresis, localized hyperthermia, electroporation, needle-free pressure jet injection, and preliminary low-frequency ultrasonication.

The eutectic mixture of local anesthetics (EMLA) cream represents a topical formulation engineered for superficial anesthesia on intact integument. Comprising an equimolar (1:1) emulsion of 2.5% lidocaine and 2.5% prilocaine in an oil-in-water matrix, EMLA exhibits a depressed melting point (18°C) relative to its individual constituents, rendering it liquid at ambient temperatures whereas the pure bases are crystalline solids. This eutectic property facilitates elevated anesthetic concentrations traversal of the keratinized epidermal barrier, obviating concerns of localized irritation, erratic absorption, or systemic toxicity. EMLA exerts its effect by percutaneous diffusion, impeding neuronal impulse transmission from dermal nociceptors [6]. Despite pervasive utilization for dermal anesthesia, its application antecedent to central neuraxial blockade for needle insertion pain attenuation remains underexplored. As a non-invasive, facile, and convenient intervention, EMLA surpasses alternative modalities in diminishing needle insertion pain and assuaging patient apprehension and anxiety [7].

EMLA has been efficaciously deployed for pain mitigation in diverse procedures, including venipuncture, arterial cannulation, phlebotomy, superficial dermatological interventions, fine-needle aspirations, episiotomy repair, peribulbar blocks, odontological procedures, epidural insertions, and lumbar punctures. It has demonstrated utility in attenuating immunization-related needle pain in infants and infiltrative anesthesia for bedside invasives. Although initially contraindicated for mucosal surfaces, EMLA has emerged as the preeminent topical anesthetic in dentistry. Notwithstanding its validated efficacy across a spectrum of cutaneous penetrative procedures, its investigation in pediatric subarachnoid blocks is

sparse.

The present investigation augments the extant corpus of knowledge on EMLA's topical utility for dermal anesthesia preceding spinal needle insertion in central neuraxial blockade for infraumbilical surgery among children aged 5-12 years. By systematically evaluating its impact on pain metrics, hemodynamic responses, procedural efficiency, and safety, this study elucidates EMLA's potential to enhance pediatric anesthetic outcomes.

AIMS AND OBJECTIVES

Aim

This investigation endeavors to delineate the analgesic potency of topical EMLA cream application antecedent to spinal anesthesia in pediatric patients aged 5-12 years.

Primary Objective

To ascertain the influence of the investigational agent on pain mitigation during spinal needle insertion, quantified via VAS scores, patient somatic responses (BPS), and hemodynamic fluctuations.

Secondary Objectives

To quantify the requisite attempts for spinal anesthesia administration and to surveil for pharmacotherapeutic adverse sequelae.

Clinical Pharmacology

Eutectic Mixture of Local Anesthetics (Lidocaine + Prilocaine)

EMLA cream constitutes a 5% amalgamation of two amide-class local anesthetics: lidocaine and prilocaine. A eutectic formulation denotes a composite with a melting temperature inferior to its constituents. Each gram of EMLA incorporates 25 mg lidocaine, 25 mg prilocaine, polyoxyethylene fatty acid esters (emulsifiers), carboxypolymethylene (viscosity enhancer), sodium hydroxide (pH adjuster to ~9), and purified water ad 1 g. Specific gravity approximates 1.00, sans preservatives.

Lidocaine

Chemically denominated as 2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide, lidocaine possesses an octanol:water partition coefficient of 43 at pH 7.4 and molecular weight 234.3.

Prilocaine

Prilocaine: N-(2-methylphenyl)-2-(propylamino)propanamide; partition coefficient 25 (pH 7.4); molecular weight 220.3. Prilocaine metabolism yields o-toluidine, potentially causing methemoglobinemia, with heightened risk in young infants due to reduced methemoglobin reductase.

Mechanism Of Action

Under occlusive dressing, EMLA releases lidocaine and prilocaine into epidermal/dermal layers, accumulating near pain receptors and nerve endings. As amide anesthetics, they stabilize neuronal membranes by inhibiting voltage-gated sodium channels, blocking action potential initiation and propagation without altering resting potential.

Onset and duration depend on application time: dermal analgesia commences at 1 hour, peaks at 2-3 hours, persists 1-2 hours post-removal. Pediatric dosing guidelines limit dose and area by age/weight to prevent toxicity [15]. Contraindicated in neonates <37 weeks gestation or infants <12 months on methemoglobinemia-inducing agents.

Pharmacokinetics

Eutectic formulation enhances penetration. Systemic absorption correlates with duration and area; increased with compromised skin. Distribution: lidocaine volume 1.1-2.1 L/kg, 70% protein-bound; prilocaine 0.7-4.4 L/kg, 55% bound. Both cross placental/brain barriers.

Metabolism: Lidocaine hepatic to monoethylglycinexylidide (MEGX) and glycinexylidide (GX); prilocaine hepatic/renal to o-toluidine (methemoglobin risk) and N-propylalanine. Vulnerable populations include young children, G6PD deficiency, and those on oxidizing drugs.

Elimination: Lidocaine half-life 65-150 min, clearance 10-20 mL/min/kg; prilocaine 10-150 min, 18-64 mL/min/kg.

Indications And Contraindications

Indicated for intact skin analgesia and mucosal pretreatment. Contraindicated in amide hypersensitivity, methemoglobinemia, or relevant drug interactions (class I antiarrhythmics, oxidizing agents).

Hyperbaric Bupivacaine

Used intrathecally (0.5% in 8.25% dextrose; specific gravity 1.0227-1.0278). Onset 5-10 min, duration 90-120 min. Highly lipid-soluble, protein-bound; pKa 8.1; metabolism hepatic; excretion renal. Acts on sodium channels, producing differential block (autonomic > sensory > motor). Safe within therapeutic doses; toxicity manifests centrally (excitation/depression) and cardiovascularly (myocardial depression, arrhythmias).

Pain Assessment

VAS: 0-100 mm scale (no pain to worst imaginable). BPS: scores facial expression, limb movements, and ventilatory compliance (though adapted here for non-ventilated patients, focusing on expression and movements).

MATERIALS AND METHODS

This prospective, randomized, double-blinded, controlled study was conducted at a tertiary hospital following Institutional Ethics Committee approval and informed parental consent. Duration: September 2023–August 2024.

Inclusion Criteria

Children aged 5-12 years, weight >15 kg, either sex, ASA physical status I-II, scheduled for elective infraumbilical surgery under spinal anesthesia.

Exclusion Criteria

Age extremes, hypersensitivity to EMLA/components, methemoglobinemia or inducing drugs, parental refusal, spinal/neuromuscular deformities, coagulopathy, local infection, hypovolemia/bradycardia, ASA≥III.

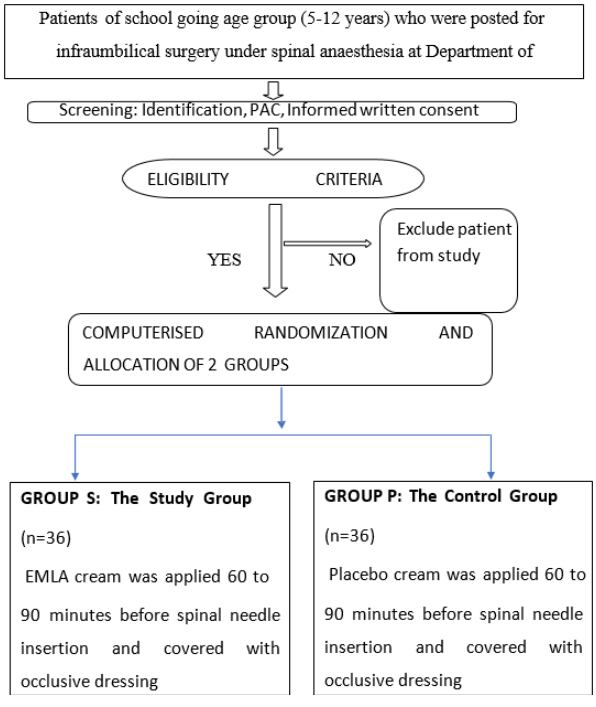
Sample Size

Calculated as 36 per group (total 72) based on prior data [18] (VAS reduction: control 3.1±1.62 vs. intervention 1.06±1.33), assuming α=0.05, power=80%, detectable difference ≥1, yielding n≈36 using Snedecor-Cochran formula.

Randomization And Blinding

Computer-generated randomization allocated patients 1:1 to Group S (EMLA) or Group P (placebo). Creams prepared/applied by uninvolved personnel; investigators and patients blinded.

FLOW CHART



Intervention
EMLA or placebo applied 60-90 minutes pre-procedure over lumbar site under occlusive dressing.

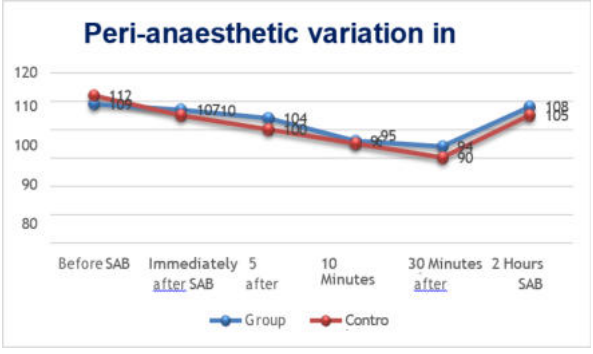
Preoperative Evaluation
History, examination, fasting instructions, routine investigations (hematology, biochemistry, radiology as indicated).

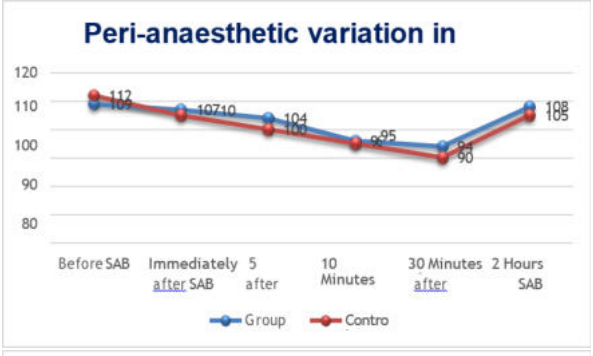
Anesthetic Technique
Standard monitoring (pulse oximetry, NIBP, ECG). IV access, fluid maintenance. Anxious/uncooperative children received midazolam 0.05 mg/kg IV. Lateral position, aseptic technique, 25-27G Quincke needle, hyperbaric bupivacaine 0.3 mg/kg. Ketamine 1 mg/kg IV if movement/anxiety during insertion. Supine positioning post-block; block success confirmed by absence of >15% hemodynamic increase on incision. Monitoring continued intra- and postoperatively.

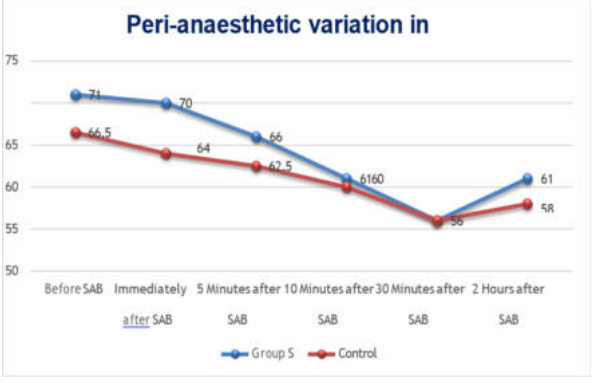
Statistical Analysis
SPSS v25 employed. Descriptive statistics, independent t-tests, ANOVA, chi-square/Fisher's exact, correlations as appropriate. Significance: $p<0.05$.

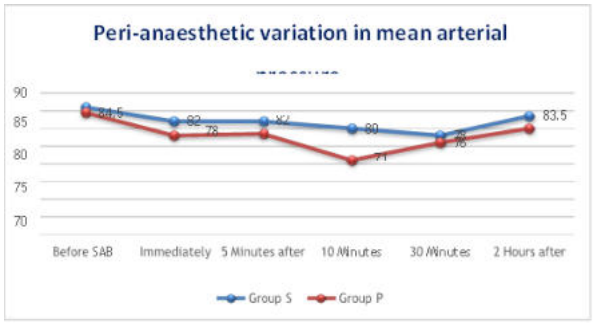
RESULTS
Demographics (age, gender, ASA status, surgical diagnosis) were comparable between groups ($p>0.05$).

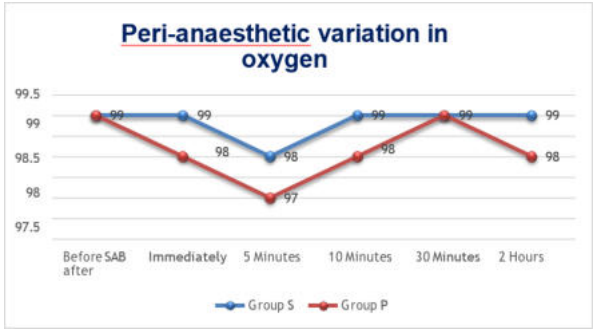
Baseline vitals equivalent. Post-insertion, Group P exhibited greater HR increase (immediate: 105±13 vs. 96±12 bpm, p=0.003; 5 min: 108±12 vs. 100±12 bpm, p=0.006). SBP/DBP/MAP declines were similar overall, but select intervals showed differences favoring Group S (e.g., DBP immediate p=0.024; MAP 2 hours p=0.021). SpO_2 minor dips in Group P at certain points ($p<0.05$).

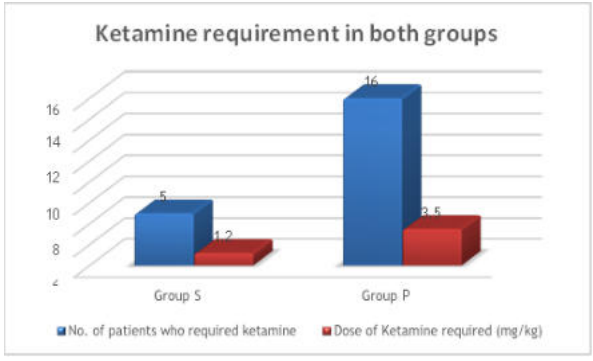












VAS (1.08±1.02 vs. 3.11±1.20; $p<0.001$) and BPS (2.00±1.00 vs. 4.20±1.10; $p<0.001$) significantly lower in Group S. Ketamine required in fewer patients (5 vs. 16; p=0.01) and lower dose (1.20±0.50 vs. 3.50±1.00 mg/kg).

Attempts marginally reduced (1.20±0.50 vs. 1.60±0.69; p=0.80). Mild local adverse effects infrequent, lower in Group S ($p<0.05$); no systemic events.

DISCUSSION
Spinal anesthesia is preferred for pediatric infraumbilical surgery due to simplicity, economy, rapid onset, muscle relaxation, minimal drug exposure, and low aspiration risk. However, fixed duration, block height variability, headache, and hypotension remain concerns. Pediatric vulnerability to needle pain anxiety underscores the need for effective mitigation.

This trial confirms topical EMLA significantly attenuates insertion pain, reflected in reduced VAS/BPS, blunted tachycardic response, diminished ketamine requirements, and enhanced cooperation. Findings align with prior studies [9-14], demonstrating lower pain scores and hemodynamic stability with EMLA versus placebo or alternatives. Marginal reduction in attempts, though non-significant, suggests improved positioning from reduced distress.

Safety profile was excellent-mild, transient local reactions only, fewer than controls-consistent with literature [15-17]. No methemoglobinemia or systemic toxicity occurred, attributable to age-appropriate dosing on intact skin.

Limitations include single-center design, modest sample, and focus on school-age children; extrapolation to younger cohorts requires caution due to methemoglobin risk. Future multicenter trials could validate broader applicability.

SUMMARY AND CONCLUSION

In this double-blinded randomized trial of 72 ASA I-II children aged 5-12 years undergoing infraumbilical surgery, topical EMLA cream applied 60-90 minutes pre-spinal significantly reduced needle insertion pain (lower VAS/BPS, $p<0.001$), attenuated hemodynamic stress responses, decreased supplemental ketamine use ($p<0.01$), and maintained safety with minimal adverse effects.

Topical EMLA cream is an efficacious, non-invasive adjunct that enhances procedural comfort, patient cooperation, and anesthetic efficiency in pediatric spinal anesthesia. Its integration into standard practice is recommended to optimize perioperative experience in school-age children.

REFERENCES

1. Gupta A, Saha U; Spinal anaesthesia in children: A review; J Anaesthesiol Clin Pharmacol. 2014Jan-Mar; 30(1): 10-18.
2. Rachel Troncin, Christophe Dadure*;* Paediatric spinal anaesthesia; Update in Anaesthesia (2009); 25,1:22-4.
3. Won Ji Rhee, Chan Jong Chung, Youn Hee Lim, Kyu Haan Lee and Seung Cheol Lee*;* Factors in patient dissatisfaction and refusal regarding spinal anaesthesia; Korean J Anesthesiol 2010 October 59(4):260-264.
4. Ran D. Goldman; Analgesia for lumbar puncture in infants and children; Canadian Family Physician (Le Medecin de famille canadien) Vol. 65: March, 2019.
5. Simone Wright et al. Aust Fam Physician; Fear of needles -- nature and prevalence in general practice.
6. Qane M, Ghiliyan R, Hashemi A, Mirmohammadi S, Keshavarzi S, Yadegar Y et al; The Efficacy of the EMLA Analgesic Cream in Compare with Placebo in Pediatric Oncology Lumbar Puncture. Iran J Ped Hematol Oncol 2012; 2 (2) :44-48.
7. P. Bjerring and L. Arendt-Nielsen; Depth and duration of skin analgesia to needle insertion after topical application of EMLA cream; British journal of anaesthesia; 1990; 64; 173-177.
8. J. Molodecka, C. Stenhouse, J. M. Jones and A. Tomlison; Comparison of percutaneous anesthesia for venous cannulation after topical application of either amethocaine or EMLA cream; British Journal of Anesthesia; 1994; 72: 174-176.
9. Shiv K. Sharma, Noor M. Gajraj, Elaine J. Sidawi and Kevin Lowe; EMLA cream effectively reduces pain of spinal needle insertion; Reg Anesth. 1996 Nov-Dec.
10. Hammad Usmani, Sarvesh Pal Singh, Abdul Quadir, R S Chana; A comparison between EMLA cream application versus lidocaine infiltration for postoperative analgesia after inguinal herniotomy in children; Reg Anesth Pain Med. 2009 Mar-Apr.;34(2):106-9.
11. Hrishikesh Walimbe, Sneha Muchandi, Mohammed Nadeem Ahmed Bijle, Vikas Bendgude, Rahul Deshpande, Arti Dolas, Shrishti Chaturvedi; Comparative evaluation of the efficacy of topical anesthetics in reducing pain during administration of injectable local anesthesia in children; World Journal of Dentistry, 2014, 5(2): 129- 133.
12. Eun Kyung Choi, YoungHo Ro, Sung-Sik Park, Ki-bum Park; The use of EMLA cream reduces the pain of skin puncture associated with caudal block in children; Korean J Anesthesiol.; 2016 Apr; 69(2): 149- 154. Published online 2016 Mar 30.
13. H Neshat, Kafiyeh Aslani, Massoud Jamshidi, Saeid Aslanbadi, Fatemeh Ghorbani ; Comparison of the effect of massage and EMLA cream on children's physiological indices during venipuncture: A factorial clinical trial; Journal of PeriAnaesthesia Nursing; Volume 35; Issue 6; December 2020, Pages 619-624.
14. Maria Anthonet Sruthi, Ganesh Jeevanandan; Efficacy of Topical Anaesthesia-Lignocaine vs. Emla in the Management of Needle Prick Pain in Children, J Res Med Dent Sci, 2020, 8 (7): 186-192.
15. Olsson Duse B, Sporrong Y, Bartocci M, Skoglund K; Efficacy of topical lidocaine-prilocaine (EMLA®) for management of infant pain during pneumococcal vaccination: A randomized controlled trial. Paediatr Neonatal Pain. 2021 Dec 24;4(2):53-60.
16. Sharma A., Sharma R., Sood M., Kumar, P.; Efficacy of eutectic mixture of local anesthetics in alleviating pain associated with lumbar puncture in newborns: a placebo compared randomized controlled trial.; Int. J. Contemp. Pediatr. 2021, 8, 1815–1818.
17. Hassan Babamohamadi et al; Comparison of the effect of EMLA™ cream and the Valsalva maneuver on pain severity during vascular needle insertion in hemodialysis patients: a controlled, randomized, clinical trial; Evidence Based Complementary and Alternnative Medicine; Volume 2022; Article ID 8383021, 9 pages.
18. Hameed M, Khan S.; Comparison of 2% lidocaine infiltration and eutectic mixture of local anesthetics cream application before spinal needle insertion for pain reduction and assessment of maternal satisfaction levels in women undergoing cesarean section at a tertiary care se. Anesth Pain Med (Seoul). 2024 May 10.