International Journal of Research in Medical Sciences
Nagabhairava MK et al. Int J Res Med Sci. 2024 May;12(5):1525-1528
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20240945

Original Research Article

Comparison of pain control between lignocaine and prilocaine spray versus oral analgesia in post-circumcision patients: a prospective randomized controlled trial in a tertiary care center

Manu K. Nagabhairava, Abhishek Kulkarni, Ameya R. Sangle, Tarun Javali*, Mani C. Reddy, Sandeep P.

Department of Urology, Ramaiah Medical College, Bengaluru, Karnataka, India

Received: 22 March 2024
Accepted: 06 April 2024

***Correspondence:**
Dr. Tarun Javali,
E-mail: tarunjavali@gmail.com

ABSTRACT

Background: Pain in the postoperative period is of particular concern. It is a major barrier in the uptake of circumcision. There are various systemic and local analgesics for the management of postoperative pain. However, data regarding efficacy is scarce. Therefore, the present pilot study was conducted to compare the efficacy of lidocaine and prilocaine spray with oral analgesics for the relief of pain.
Methods: After obtaining ethics approval and written informed consent, 100 patients meeting the inclusion and exclusion criteria were included. After circumcision, patients were randomized into group A (Lidocaine and prilocaine spray) and group B (Oral analgesics). Pain was assessed by visual analogue scale (VAS) score and patient reported comfort levels were assessed in the postoperative period till 72 hours. Findings were noted and analysed.
Results: Both the groups were similar in terms of demographic characteristics and baseline characteristics. The VAS score was significantly lower in group A and the patient-reported comfort level was significantly more in group A.
Conclusions: We recommend that the lidocaine and prilocaine spray is better in relieving pain in the postoperative period following circumcision as compared to oral analgesics.

Keywords: Circumcision, Lidocaine and prilocaine spray, Oral analgesics, Postoperative pain relief

INTRODUCTION

Circumcision is the surgical removal of foreskin covering glans penis. It is one of the most commonly performed surgery. It has a variety of indications including medical and cultural factors and personal preferences. The uptake of circumcision in adults has many barriers, particularly, postoperative pain.[1-3] Adequate pain management is critical for assuring patient comfort and satisfaction, as well as encouraging optimal surgical results. Furthermore, inadequate pain relief during and after surgery may lead to altered sensory processing and lowered threshold of painful stimuli in future.[4-6]

Various techniques have been used to relieve the pain. These include various anesthetic techniques including blocks and oral analgesics, each having their own set of side effects. The anesthetic block, like the dorsal penile block, involves needle for infiltration of local anesthetic, causing pain, increase in fear perception, occasional hematoma, edema and serious systemic side effects associated with accidental intravascular injection of the anesthetic agent.[7] Oral analgesics need to be absorbed through gut and reach a peak blood level for their action. Hence, there is delay in onset of action and are not beneficial in patients having diseases affecting absorption. Harmful blood levels may reach in patients having diseases of liver or kidney affecting their

metabolization and excretion. Additionally, there are systemic side effects, like nausea and vomiting, associated with most of the oral medicines.

Consequently, there was a search for safe, effective and simple method technique. There has been recent growing interest in topical anesthetics. One such anesthetic is the lidocaine and prilocaine administered through a metered-dose controlled aerosol spray. Topical sprays have needle-free administration (as with the blocks) and also have shorter duration of onset of action and devoid of systemic side effects (as with oral analgesics). However, data regarding their efficacy is scarce. Therefore, in the present pilot study, we assessed and compared the efficacy of lidocaine and prilocaine spray with oral analgesics in relieving post-circumcision pain in the adults.

METHODS

This prospective randomized controlled trial was conducted under the department of urology, M.S. Ramaiah medical college, Bengaluru. Patients consenting to participate in the study and who met the inclusion and exclusion criteria as below, were included in the study.

Inclusion criteria

Male patients aged 18 to 65 years, patients undergoing circumcision and patients giving consent to participate in the study were included in study.

Exclusion criteria

Patients aged less than 18 years or above 65 years, patients allergic to any of the study drugs and patients not giving consent to participate in the study were excluded from study.

All the patients attending OPD during the study period and undergoing circumcision were considered for inclusion in the study. After taking approval of the institutional ethics committee and voluntary written informed consent from all the patients, they were included in the study. A total of 100 cases meeting the inclusion and exclusion criteria, were included in the study.

Baseline demographic characteristics were noted for all patients. Detailed past and personal histories were recorded. After taking fitness for anesthesia, patients underwent circumcision as per the standard guidelines.

The patients were randomly divided into two groups: Group A (Lignocaine plus prilocaine spray) and group B (oral analgesics). The randomization was done as per consolidated standards of reporting trials (CONSORT) 2010.

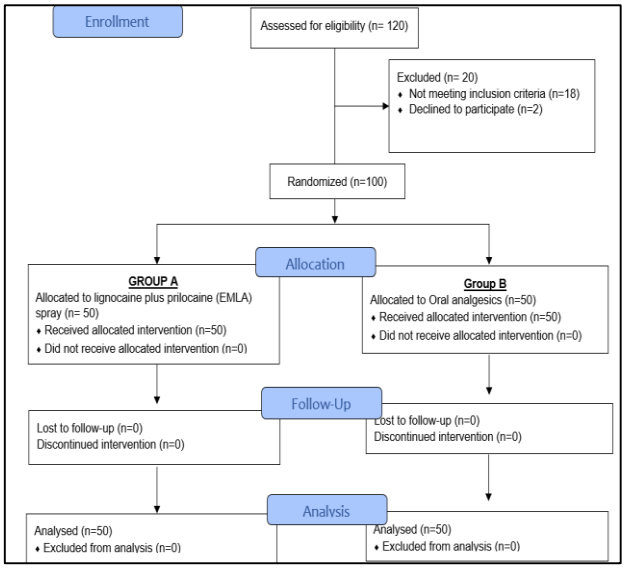

Figure 1: CONSORT 2010 flow diagram.

Group A patient's received lidocaine and spray containing lignocaine (7.5 mg) plus prilocaine (2.5 mg) per actuation. The spray was applied by the treating surgeon who ensured adequate coverage of the surgical site. Patients were instructed to reapply the spray every 4-6 hours (as needed for pain relief) for up to 72 hours postoperatively. Group B patients received either tab. ibuprofen (400 mg three times daily) or tab. acetaminophen (500 mg every 4-6 hours up to a maximum of 3,000 mg per day), as determined by the treating physician based on the patient's medical history, contraindications, and potential drug interactions. Patients were instructed to take the medication as needed for pain relief for up to 72 hours postoperatively.

The pain score was determined by the VAS with scores ranging from 0 to 10; 0 being no pain and 10 being the worst pain. The pain score was assessed at baseline and at 24 hours, 48 hours and 72 hours. The patient reported comfort level was measured on a 5-point Likert scale with 1 being very uncomfortable and 5 being very pleasant. Adverse reactions, if any, were noted.

The data was analysed using the SPSS software version 22.0. All the qualitative data was expressed as percentages. The p values were assessed by Chi square test (Fischer's exact test was used when more than 20% of the cells had value less than 5). All the quantitative data was expressed as mean ± standard deviation. P values were assessed by the unpaired t test. P value of less than 0.05 was considered as "statistically significant" and indicated by "*" in the Tables.

RESULTS

The two Groups were comparable in terms of demographic characteristics and baseline physical examination (Table 1).

Table 1: Distribution of demographic and baseline characteristics in the study population.

Parameters	Group A	Group B	P value
Age (in years)	36.4±11.2	35.8±10.4	0.465
Weight (kg)	72.3±12.1	71.6±11.9	0.078
Height (cm)	174.5±6.8	173.8±7.1	0.343

When assessed according to the indications for circumcision, it was observed that medical was the predominant indication in both the groups (Table 2).

Table 2: Distribution of indications of circumcision in the study population.

Parameters	Group A	Group B	P value
Medical	25 (50%)	28 (56%)	0.632
Religious	15 (30%)	12 (24%)	
Cultural	10 (20%)	10 (20%)	

The mean pain scores were similar in the two groups at baseline. However, at 24 hours, 48 hours and 72 hours, the pain scores were significantly lower in group A as compared to group B (Table 3).

Table 3: Distribution of pain scores in the study population.

Parameters	Group A	Group B	P value
At baseline	6.2±1.5	6.1±1.4	0.435
At 24 hours	2.5±1.0	4.6±1.2	<0.001*
At 48 hours	1.8±0.9	3.2±1.1	<0.001*
At 72 hours	1.3±0.8	2.5±1.0	<0.001*

*P value of less than 0.05 considered as statistically significant.

The patient reported comfort levels were significantly higher in group A as compared to group B at all points of time (Table 4).

Table 4: Distribution of patient reported comfort levels in the study population.

Parameters	Group A	Group B	P value
At 24 hours	4.3±0.7	2.9±0.8	<0.001*
At 48 hours	4.6±0.6	3.3±0.7	<0.001*
At 72 hours	4.8±0.4	3.6±0.6	<0.001*

*P value of less than 0.05 considered as statistically significant.

The incidence of adverse effects was 6% in both the groups. In group A, mild itching and burning at the application site were reported while in group B, gastrointestinal side effects of nausea and vomiting were reported. All the adverse effects were self-limiting and resolved without any additional intervention.

DISCUSSION

In the present study, we observed that the postoperative pain relief was significantly better with lidocaine and prilocaine spray as compared to oral analgesics along with better patient-reported comfort scores.

Both the drugs have different mechanism of action. It has been hypothesized that lidocaine and prilocaine spray increases the threshold of nerve excitation in the free nerve endings and thereby suppresses the initiation and transmission of nerve impulses.[8] On the other hand, non-steroidal anti-inflammatory drugs (NSAIDs) alleviate the nociceptive response to the inflammatory mediators. They reduce the tissue concentration of prostaglandins by inhibiting the cyclo-oxygenase (COX) enzyme.[9]

Many studies have been conducted to assess the pain relief during and after circumcision in neonates by application of lidocaine and prilocaine spray and compare it with various pharmacological and non-pharmacological interventions and placebo. Lidocaine and prilocaine spray was found to be inferior to DPNB for the relief of intraoperative pain.[10,11] Some studies have found lidocaine and prilocaine spray to be effective in combination with other analgesic strategies while in other studies it was found to be comparable to DPNB and lidocaine cream.[12-16]

Lidocaine and prilocaine spray is the preferred local anesthetic as unlike the previous formulations, it allows use of higher concentrations of the anesthetic drug with lower concerns of local irritation, absorption and systemic toxicity. It also has a lower melting point than either of its constituents which may account for its higher skin permeability.[17] It has also been shown to be effective in pain relief following cutaneous procedures. We used spray in present study as spray ensures even distribution of drug, therefore, elimination the risk of subtherapeutic concentrations in some regions. In the case of a proper circumcision, three parts of penis have to be anesthetized: The penile shaft skin, the inner layer of the prepuce and especially the ridged band and the mostly sensitive frenular area. Clearly, spray form allows better reach, coverage and even distribution of the anesthetic drug, as compared to gel and other forms of topical applications.

Therefore, present study proves that the local application of lidocaine and prilocaine spray ensures better pain relief of post-circumcision pain compared to oral analgesics, provided they are reapplied at pre-defined intervals.

Limitations

This pilot single center study is limited by the OPD attendance of the patients undergoing circumcision. Therefore, the results may not be generalized.

CONCLUSION

Pain in the postoperative period is bothersome in patients undergoing circumcision. Pain relief, especially in postoperative period, is crucial to the recovery. Topical agents have an edge over the anesthetic and oral

analgesics due to ease of administration and faster onset of actions.

It can be concluded from the present study that lidocaine and prilocaine sprays are more effective than oral analgesics in reducing the pain and increasing the comfort in the postoperative period following circumcision, provided reapplication at proper predefined intervals.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Westercamp N, Bailey RC. Acceptability of male circumcision for prevention of HIV/AIDS in sub-Saharan Africa: a review. AIDS Behav. 2007;11(3):341-55.
2. Mattson CL, Bailey RC, Muga R, Poulussen R, Onyango T. Acceptability of male circumcision and predictors of circumcision preference among men and women in Nyanza Province, Kenya. AIDS Care. 2005;17(2):182-94.
3. Ngalande RC, Levy J, Kapondo CP, Bailey RC. Acceptability of male circumcision for prevention of HIV infection in Malawi. AIDS Behav. 2006;10(4):377-85.
4. Wang J, Zhao S, Luo L, Liu Y, Zhu Z, Li E, et al. Dorsal penile nerve block versus eutectic mixture of local anesthetics cream for pain relief in infants during circumcision: A meta-analysis. PLoS One. 2018;13(9):e0203439.
5. Peters JW, Schouw R, Anand KJ, van Dijk M, Duivenvoorden HJ, Tibboel D. Does neonatal surgery lead to increased pain sensitivity in later childhood? Pain. 2005;114(3):444-54.
6. Taddio A, Katz J. The effects of early pain experience in neonates on pain responses in infancy and childhood. Paediatr Drugs. 2005;7(4):245-57.
7. Zilbert A. Topical anesthesia for minor gynaecological procedures: A review. Obstet Gynecol Surv. 2002;57:171-8.
8. Kim JE, Kim JY, Lee HS, Seok S, Kil HK. Analgesic effect of trigger point injection and EMLA for shoulder pain in patients undergoing total laparoscopic hysterectomy: A randomized controlled study. Medicine (Baltimore). 2019;98(2):e14087.
9. Chandrasekharan NV, Dai H, Roos KL, Evanson NK, Tomsik J, Elton TS, et al. COX-3, a cyclooxygenase-1 variant inhibited by acetaminophen and other analgesic/antipyretic drugs: cloning, structure, and expression. Proc Natl Acad Sci U S A. 2002;99(21):13926-31.
10. Garry DJ, Swoboda E, Elimian A, Figueroa R. A video study of pain relief during newborn male circumcision. J Perinatol. 2006;26(2):106-10.
11. Modekwe VI, Ugwu JO, Ekwunife OH, Osuigwe AN, Obiechina SO, Okpalike IV, et al. Comparison of the efficacy of eutectic mixture of local anesthetics (EMLA) and dorsal penile nerve block (DPNB) in neonatal circumcision. Niger J Clin Pract. 2019;22(12):1737-41.
12. Al Qahtani R, Abu-Salem LY, Pal K. Effect of lidocaine-prilocaine eutectic mixture of local anaesthetic cream compared with oral sucrose or both in alleviating pain in neonatal circumcision procedure. Afr J Paediatr Surg. 2014;11(1):56-61.
13. Sharara-Chami R, Lakissian Z, Charafeddine L, Milad N, El-Hout Y. Combination Analgesia for Neonatal Circumcision: A Randomized Controlled Trial. Pediatrics. 2017;140(6):e20171935.
14. Choi WY, Irwin MG, Hui TW, Lim HH, Chan KL. EMLA cream versus dorsal penile nerve block for postcircumcision analgesia in children. Anesth Analg. 2003;96(2):396-9.
15. Lehr VT, Cepeda E, Frattarelli DA, Thomas R, LaMothe J, Aranda JV. Lidocaine 4% cream compared with lidocaine 2.5% and prilocaine 2.5% or dorsal penile block for circumcision. Am J Perinatol. 2005;22(5):231-7.
16. Lehr VT, Zeskind PS, Ofenstein JP, Cepeda E, Warrier I, Aranda JV. Neonatal facial coding system scores and spectral characteristics of infant crying during newborn circumcision. Clin J Pain. 2007;23(5):417-24.
17. Vickers ER, Marzbani N, Gerzina TM, McLean C, Punnia-Moorthy A, Mather L. Pharmacokinetics of EMLA cream 5% application to oral mucosa. Anesth Prog. 1997;44(1):32-7.

Cite this article as: Nagabhairava MK, Kulkarni A, Sangle AR, Javali T, Reddy MC, Sandeep P. Comparison of pain control between lignocaine and prilocaine spray versus oral analgesia in post-circumcision patients: a prospective randomized controlled trial in a tertiary care centre. Int J Res Med Sci 2024;12:1525-8.