

The effectiveness of diclofenac gel and eutectic mixture of local anesthetic cream on vein puncture pain severity with vein catheter in patient undergoing cesarean section: A randomized, double-blind, placebo-controlled trial

Sediqueh Khalili, Mahboubeh Safavi¹, Rozita Rezaei², Maria Bidmeshki³, Fatemeh Shirzad³, Mostafa Nasiri⁴

Department of Nursing and Midwifery, Sabzevar University of Medical Sciences, Sabzevar, Iran and Shohada Hospital, Mahmood Abad, Mazandaran University of Medical Sciences, ²Department of Nursing and Midwifery, Mazandaran University of Medical Sciences, ³Shohada Hospital, Mahmood Abad, Mazandaran University of Medical Sciences, Sari, ¹Department of Nursing, Islamic Azad University, Tehran Medicine Branch, Tehran, ⁴Computer Engineering, Tamin Ejtemai Amol, Mazandaran, Iran

ABSTRACT

Aim: This study was aimed to explore the effect of applying diclofenac gel and a eutectic mixture of local anesthetic (EMLA) cream on vein puncture pain severity with vein catheter in the patients undergoing cesarean section. **Materials and Methods:** The sample comprised 90 women undergoing elective cesarean section that referred to Imam Ali Hospital's maternity section in Amol city (Northern Iran). Data collection tools included visual analog scale for pain severity and a checklist for short term possible side-effects of diclofenac gel, EMLA cream and Vaseline ointment as placebo. **Results:** The pain of vein puncture with diclofenac gel and EMLA cream was significantly lower than that with the Vaseline ointment ($P = 0.001$). Similarly, there was a significant difference between using diclofenac gel and EMLA cream in catheter insertion pain severity ($P = 0.006$). In addition, there was no short term possible side-effect with using diclofenac gel and Vaseline ointment, but a short term side-effect (blanching) was detected in 20% of subjects with EMLA cream. **Conclusion:** Compared to Vaseline cream, EMLA cream and diclofenac gel application significantly reduces the pain severity associated with vein catheter insertion. Use of diclofenac gel is preferred compared with EMLA cream, because of economics, more efficiency purpose, and no side-effects.

Key words: Diclofenac gel, eutectic mixture of local anesthetic cream, pain, vein puncture

Submission: 11-08-2013 **Accepted:** 07-03-2014

INTRODUCTION

Venous cannulation is the most common invasive procedures in several patients in hospital, including anesthesiologists daily.^[1]

Address for correspondence: Mr. Mostafa Nasiri,
Computer Engineering, Tamin Ejtemai Amol, Hraz avenue,
Amol, Mazandaran, Iran.
E-mail: Khalilnurse950@gmail.com

It leads to unwanted effects like pain, especially among patients who fear of needles. Fear of needles and pain associated with vein puncture is a common phobia in the general population.^[2] Fear of pain and anxiety associated with venous cannulation may contribute to the overall stress experienced by patients in the preoperative setting.^[3,4]

According to Shaikh *et al.* there is a lack of cooperation, low rate of the successful procedure attempts, repeated attempts, additional pain, and a prolonged total procedure time. Injection-injury consequently leads to avoidance among patients from medical care and blood donating or precipitating fainting episodes.^[5] Therefore, the healthcare providers recommended some methods to alleviate pain during the injections. In addition, patients are often more satisfied with their doctors when they are treated by methods having minimal or no pain.^[6] Considering

Access this article online	
Quick Response Code:	Website: www.ijabmr.org
	DOI: 10.4103/2229-516X.140739

premedication relieves the anxiety and fear associated with pain as well as the pain itself. Choosing the more effective analgesia is required to reduce the actual pain experienced.^[2] The effect of various pharmacological and nonpharmacological measures has been explored in several studies in order to minimize venous cannulation pain.^[7,8]

However, there are a few cost-effective, simple and effective methods associated with pain reduction during venous cannulation.^[9] These methods commonly comprised local skin infiltration, topical application of eutectic mixture of local anesthetics (EMLA) or nonsteroid anti-inflammatory drugs (NSAIDs), topical alkaline vapocoolant spray, ibuprofen, etc.^[1,10-12] Nevertheless, analgesia is an integral part of anesthesia management.^[13] One of pain methods is injection. Injections in general and especially the placement of intravenous cannula are often the cause of pain and anxiety for many patients. However, there is no “gold standard” and there is a need for the development of innovative analgesic methods that are simple to use, painless, effective with a minimal delay, without adverse effects, and cost-effective.^[7] Thus, clinical practice has recently interested to incorporate various techniques for decreasing the discomfort and pain of procedures involving routine needle punctures, such as vein puncture, intravenous catheter placement, and lumbar puncture.^[14] One of these methods is applying the EMLA. EMLA, a local anesthetic cream composed of a eutectic mixture of lidocaine and prilocaine provides.^[7] Hence, a topical formulation may offer substantial benefits for prevention of needle and procedural pain. A eutectic mixture of lidocaine and prilocaine (EMLA) is the first commercially developed topical transdermal anesthetic agent that provides adequate effective analgesic properties.^[6] Therefore, we aimed to compare the effect of EMLA cream and diclofenac gel in pain reduction in patients undergoing caesarian section surgery.

MATERIALS AND METHODS

This controlled, randomized clinical trial study has assessed the effect of diclofenac gel, EMLA and placebo on vein puncture pain. Formal consent was filled for all patients. This study approved by the Ethical Committee of Islamic Azad University of Tehran. The registration ID of study is Registration ID in IRCT IRCT201008234618NI.

Sampling

Ninety women aged 18-40 years old who were referred to Imam Ali Hospital for elective cesarean section during 2010, were selected randomly through random scheduling. Exclusion criteria include addiction to opium or analgesics, mental, visual and verbal inability, use of analgesic in last 24 h, anaphylactic response to NSAID. Considering inclusion and

exclusion criteria and homogeneity of samples, the researchers selected patients in cesarean section. Patients were allocated into three groups, diclofenac ($N = 30$), EMLA ($N = 30$) and placebo ($N = 30$).

Sample size

A sample size of 30 patients was calculated considering statistical power of 0.8 ($\beta=1$) and average effect of $d = 0.7$.

Tools

The questionnaire includes socio demographic characters, i.e. age and weights were collected and visual analog scale (VAS) was used to find the pain severity induced by venous puncture. The side-effects of drugs were also recorded. One hour before puncture, 2 g EMLA (compound of 2.5% prilocaine, and 2.5% lidocaine Tehran chemistry, Iran) covered the skin (2.5 cm × 4 cm) in the second group, diclofenac gel (1%) (Behvasan, Rasht) (1.9 cm × 3.8 cm) was covered for patients left hand, and in the third group, placebo (Vaseline, Pars Hayan, Iran) include liquid and glycerine without lanolin and essence) was covered on patient's left hand. After 60 min ointments and gel were cleaned from the hand and side-effects were recorded. Then, venous puncture was done by angiocath number 3-5 min after puncture, pain was recorded by VAS. The pain level categorization applied according Polit and Beck manual.^[14] The nurses who assessed the patients were blind to the design of the study.

Statistical analysis

Beside descriptive method to calculate mean and standard deviation, we used ANOVA and K^2 to analysis the sample demographic characters. Mann-Whitney used to compare pain severity level in paired groups. Data were analyzed by software SPSS-16 (IBM corp, USA- Chicago).

RESULTS

A total of 90 cases allocated in three groups, i.e. diclofenac ($N = 30$), EMLA cream ($N = 30$) and placebo ($N = 30$). Because of short term intervention there was no drop-out during interventions. The findings of the current study showed that there was no significant difference in demographic variables between the three groups at baseline in respect of age, weight and height [Table 1]. In addition, there was no significant difference in education ($P = 0.957$) and place of residence ($P = 0.861$).

The distribution of pain severity during vein puncture in three groups is shown in Table 2. Our results showed that mild pain was more frequent in the diclofenac group versus two other groups [Figure 1]. The mean and standard deviation of pain severity in the placebo group

Table 1. Demographic data presented either as number of patients or mean±SD

Group demographic	Diclofene	Elma	Placed	P value (Anore)
Age	27.8±3.84	28.2±5.37	28.36±4.54	0.890
Height	163±4.03	163.4±33.76	161.57±3.91	0.169
Weight	84.31±8.22	82.53±8.76	80.73±7.06	0.229

SD: Standard deviation

Table 2: Frequency of pain severity induced by vein puncture in 3 groups by visual analog scale in patients undergoing cesarean section

Group pain severity	Diclofenac		EMLA		Placebo	
	N	%	N	%	N	%
No pain	0	0	1	3.33	0	0
Mild pain	28	93.33	19	63.33	0	0
Moderate pain	2	6.66	10	33.33	28	93.33
Severe pain	0	0	0	0	2	6.66
Total	30	100	30	100	30	100
Mean	1.76		2.3		4.66	

EMLA: Eutectic mixture of local anesthetic

was 4.66 ± 1.02 , EMLA group 2.3 ± 0.9 and 1.76 ± 0.91 in diclofenac group. Hence, it is clear that the least pain was observed in diclofenac group and placebo has the most pain severity during vein puncture.

Comparing pain severity induced by vein puncture using in pair groups, we found that the placebo group had significantly more pain severity than diclofenac and EMLA groups ($P = 0.001$). Furthermore, mean of pain severity in diclofenac and EMLA groups was 1.76 and 2.3, respectively ($P = 0.006$).

Whitening, redness, urticarial, and itching were the short side-effects of local drugs and were appearing in 1 h after drug prescription. Our results showed that in about 20% of EMLA ointment whitening was appeared, and 80% of patients, no side-effect was appeared. In two other groups, no side-effect was observed. Our results showed that there was a significant difference between group in relation with side-effects ($P = 0.0001$).

DISCUSSION

The results of our study showed that 93.33% of patients in diclofenac group and 63.33% in EMLA group had mild pain and 93.33% of patients in the placebo group had moderate pain during vein puncture. Mean score of pain severity were 4.66, 2.3, and 1.76 in the placebo, EMLA and diclofenac groups, respectively. There was significant difference between the three groups in pain severity ($P = 0.001$). These findings are similar to the results of other findings conducted in Iran.

Arafi et al. evaluated pain severity in three group, i.e. sucrose 25% basement cream, EMLA cream and Vaseline. They reported

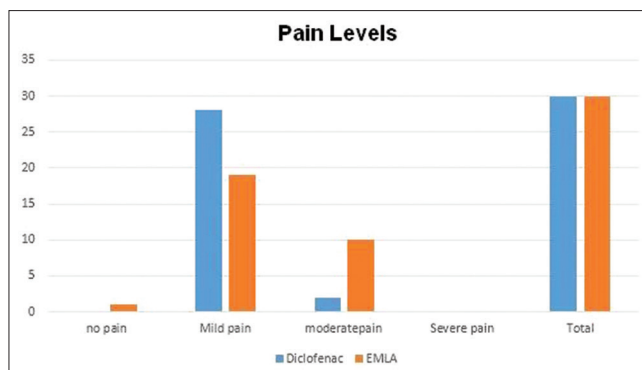


Figure 1: Effectiveness of diclofenac and EMLA on pain

that there was a significant difference between the three groups ($P = 0.001$).^[15]

The results comparing vein puncture pain between groups in current study indicated that pain severity in diclofenac group was less than EMLA group and the difference was significant ($P = 0.006$). Agarwal et al. also compared the effect of diclofenac patch, EMLA cream and Vaseline patch in pain reduction of 450 patients during vein puncture and indicated that all patients in the control group experienced vein puncture pain, but there was 37% pain reduction in EMLA group and 48% pain reduction in diclofenac patch ($P < 0.001$).^[13]

Our results also showed that placebo group experience more pain compared with diclofenac and EMLA group ($P = 0.001$). Similar to our findings the results of Saxena et al. showed that the mean pain severity in EMLA group was less than Vaseline group ($P < 0.001$).^[2] Agarwal et al. also reported that there is a significant difference in pain reduction between diclofenac patch and placebo patch ($P < 0.005$),^[13] which is in harmony with our findings of current study.

In last decades, several researches have been conducted aimed to evaluate effectiveness of medicines. However, rare studies exist targeted to examine the effectiveness of topical nonsteroidal anti-inflammatory drugs. Totally, the findings of the current study revealed that pain severity in diclofenac group was lower than placebo and EMLA cream. This finding is in harmony with a study done by Deshpande et al., who reported higher effectiveness of diclofenac patch in comparing to EMLA among adult patients underwent surgery.^[16]

In addition, we explored the probable side-effects of drugs (diclofenac gel, EMLA and baseline) which indicated the side-effects, mostly was blanching, redness, urticarial, and pruritus mostly occurred our hour after vein puncture, the most common side-effect was blanching in the EMLA group which was present in 20% of cases and in 80% of cases there

were no side-effects. Dutta *et al.* showed that blanching is a common side-effect of EMLA in the hour of use.^[9]

CONCLUSION

According to our findings EMLA and diclofenac gel reduce vein puncture pain significantly compared with placebo. However, we suggest using diclofenac gel rather than EMLA because it is more cost-effective and effective in the reduction of pain with less side-effects. Hence, we suggest that there should be some policies in health care centers and treatment clinics of our country in a different ward to use diclofenac gel as a choice to vein puncture pain.

There was some limitation in this study such as small samples. We did not measure the anxiety level of samples, which is extremely related to pain severity. The samples selected only from one center. We could not measure the effect of pain severity on birth related outcomes.

REFERENCES

- Deshpande CM, Jain V. Comparison between diclofenac transdermal patch vs transdermal EMLA (eutectic mixture of local anaesthetic) cream for attenuation of pain of venous cannulation. *J Anaesth Clin Pharmacol* 2010;26:231-6.
- Saxena KN, Dua CK, Taneja AB. Comparative evaluation of lignocaine gel vs EMLA cream for pain free intravenous cannulation. *J Anaesth Clin Pharmacol* 2004;20:279-82.
- Agarwal A, Gautam S, Gupta D, Singh U. Transdermal diclofenac patch vs eutectic mixture of local anesthetics for venous cannulation pain. *Can J Anaesth* 2007;54:196-200.
- Nir Y, Paz A, Sabo E, Potasman I. Fear of injections in young adults: Prevalence and associations. *Am J Trop Med Hyg* 2003;68:341-4.
- Shaikh FM, Naqvi SA, Grace PA. The influence of a eutectic mixture of lidocaine and prilocaine on minor surgical procedures: A randomized controlled double-blind trial. *Dermatol Surg* 2009;35:948-51.
- Hariharan S, Ramsewak R, Chen D, Merritt-Charles L, Bridglal C. A study of the efficacy of diclofenac iontophoresis for providing effective topical analgesia. *Indian J Pharm Sci* 2007;5:1-10.
- Bellieni CV, Cordelli DM, Raffaelli M, Ricci B, Morgese G, Buonocore G. Analgesic effect of watching TV during venipuncture. *Arch Dis Child* 2006;91:1015-7.
- Gupta D, Agarwal A, Dhiraaj S, Tandon M, Kumar M, Singh RS, *et al.* An evaluation of efficacy of balloon inflation on venous cannulation pain in children: A prospective, randomized, controlled study. *Anesth Analg* 2006;102:1372-5.
- Dutta A, Puri GD, Wig J. Piroxicam gel, compared to EMLA cream is associated with less pain after venous cannulation in volunteers. *Can J Anaesth* 2003;50:775-8.
- Agarwal A, Yadav G, Gupta D, Tandon M, Singh PK, Singh U. The role of a flash of light for attenuation of venous cannulation pain: A prospective, randomized, placebo-controlled study. *Anesth Analg* 2008;106:814-6.
- Hijazi R, Sztudent M, Taylor D. Effect of topical alkaline vein puncture spray on pain with intravenous cannulation in patients in emergency departments: Randomized double blind placebo controlled trial. *Director of emergency and general medicine research. BMJ* 2009;338:357-9.
- Smith AJ, Eggers KA, Stacey MR. Topical ibuprofen for skin analgesia prior to venepuncture. *Anaesthesia* 1996;51:495-7.
- Agarwal A, Dhiraaj S, Kumar A, Singhal V, Singh U. Evaluation of a diclofenac transdermal patch for the attenuation of venous cannulation pain: A prospective, randomised, double-blind, placebo-controlled study. *Anaesthesia* 2006;61:360-2.
- DF, Beck C. *Essentials of Nursing Research: Methods, Appraisal, and Utilization*. 6th ed, Philadelphia, Wolters Kluwer Lippincott, Williams and Wilkins; 2006.
- Arafi H, Eslami Z, Norishadcom M, Manochehri Naieni M, Jalalpor SO, Abyari SA. Comparison of the effect EMLA cream and orally administered Sokoros solution in reduction of pain in newborns during vein puncture. *Iran Red Crescent Med J* 2008;15:9-13.
- Deshpande CM, Jain V. Comparison between diclofenac transdermal patch vs transdermal EMLA (eutectic mixture of local anaesthetic) cream for attenuation of pain of venous cannulation. *J Anaesth Clin Pharmacol* 2010;26:231-6.

How to cite this article: Khalili S, Safavi M, Rezaei R, Bidmeshki M, Shirzad F, Nasiri M. The effectiveness of diclofenac gel and eutectic mixture of local anesthetic cream on vein puncture pain severity with vein catheter in patient undergoing cesarean section: A randomized, double-blind, placebo-controlled trial. *Int J App Basic Med Res* 2014;4:46-9.

Source of Support: Nill. **Conflict of Interest:** None declared.