# The Effect of Eutectic Mixture of Local Anesthetic Cream on the Wrist Pain during Trans-Radial Coronary Procedures

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# The Effect of Eutectic Mixture of Local Anesthetic Cream on the Wrist Pain during Trans-Radial Coronary Procedures

A Master's thesis

Submitted to the Department of Medicine

and the Graduate School of Yonsei University

in partial fulfillment of the

requirements for the degree of

Master of Medical Science

Jang-Young Kim

July 2004 of submission

This certifies that the Master's thesis
of Jang-Young Kim is approved.

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July 2004

# 감사의 글

먼저 본 논문이 아이디어, 연구 과정, 논문 작성의 모든 과정을 지도해 주시고, 논문을 작성하는 것이 즐겁고 보람 있는 작업임을 일깨워 주신 윤정한 교수님께 감사 드립니다.

학위 논문의 의의 및 논문 내용에 대해 조언을 해주신 최경훈 교수님, 논문 내용을 세심히 검토해 주시고 교정을 해주신 고창만 교수님 진심으로 감사 드립니다. 연구 과정에서 조언을 해주신 이승환, 유병수 교수님께도 감사 드립니다. 또한 바쁜 일과에도 연구를 불평 없이 열심히 도와준 심혈관 조영실의 직원 분들께 (특히 유정미님) 감사 드립니다.

끝으로 저희 가족의 사랑과 든든한 후원자가 되어 주시는 아버님, 어머님, 장인, 장모님과, 세 아이를 키우느라 고생하는 사랑하는 아내 김성희와 기쁨을 함께하고 싶습니다.

2004년 7월

저자 씀

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# Abstracts

## The Effect of Eutectic Mixture of Local Anesthetic Cream on the Wrist Pain during Trans-Radial Coronary Procedures

Radial artery cannulation for transradial coronary procedures is painful. The standard method of providing analgesia for this technique is infiltration of the skin and subcutaneous tissue with lidocaine by using a small gauge needle. However, local infiltration of anesthetic at the wrist is painful. A eutectic mixture of local anesthetic (EMLA) cream, composed of lidocaine 2.5% and prilocaine 2.5%, is known to be an effective topical anesthetic agent, and it is used for a variety of painful cutaneous procedures.

The aim of the study was to evaluate the effects and optimal application time of an EMLA cream in relieving the wrist pain during trans-radial coronary procedures. A prospective, randomized, double-blind clinical trial was undertaken to compare the pain grade of the radial puncture site after application of EMLA cream to placebo cream in 400 patients who underwent transradial coronary procedures. EMLA cream was applied at the puncture site for 0-1, 1- 2, 2-3, and $\geq$ 4 hour before the procedure, and we evaluated the pain threshold by the visual analogue scale (VAS) or four-category verbal rating scale (VRS-4) and complications.

EMLA cream demonstrated greater pain relief compared with placebo, as determined by VAS (control: 49 $\pm$ 24, EMLA: 19 $\pm$ 22, p=0.001) and VRS-4 (control: 2.3 $\pm$ 0.5, EMLA: 1.5 $\pm$ 0.6, p=0.001), and there was significant negative correlation (r= -0.476, p=0.001) between VAS score and the duration of EMLA cream application. In the EMLA group, there was no difference in the pain score between the control and 0-1 hour group as determined by VAS (control: 49 $\pm$ 24, $EMLA_{0\text{-}1\ hour}$: 45 $\pm$ 30, p=0.89) and VRS-4 (control: 2.3 $\pm$ 0.5, $EMLA_{0\text{-}1\ hour}$: 2.2 $\pm$ 0.7, p= 0.92). However, there was a significant difference in the pain score between the control and 1-2 hour group as determined by VAS (control: 49 $\pm$ 24, $EMLA_{1\text{-}2\ hour}$: 28 $\pm$ 26, p=0.001) and VRS-4 (control: 2.3 $\pm$ 0.5, $EMLA_{1\text{-}2\ hour}$: 1.7 $\pm$ 0.6, p= 0.001). Drug-induced local erythema frequently occurred in the 3-4 hour (6.6%) and > 4 hours (11.9%) groups.

In conclusion, EMLA cream can be effective in reducing the wrist pain during arterial cannulation for trans-radial coronary procedures without any significant drug-related complications, when the application time is 1 to 3 hour before the start of the procedure.

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Key words: anesthetics, radial artery cannulation, EMLA cream

# The Effect of Eutectic Mixture of Local Anesthetic Cream on the Wrist Pain during Trans-Radial Coronary Procedures

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(Directed by Professor Junghan Yoon)

## 1. Introduction

A eutectic mixture of local anesthetic (EMLA) cream, composed of lidocaine 2.5% and prilocaine 2.5%, is known to be an effective topical anesthetic agent. It is used for a variety of painful cutaneous procedures on intact skin, including phlebotomy, intravenous catheterization, arterial cannulation, and lumbar puncture. [1-3]

There has been growing interest in transradial coronary procedures because of

rare complications at this puncture site, no need to limit the patient's activity, or early discharge. [4, 5] Furthermore, more availability of radial artery as a vascular access route are expected to expand due to the miniaturization and improvement of the devices used, improvement of the techniques, and the accumulated experiences on trans-radial coronary procedures. However, the major discomfort of patients who underwent trans-radial coronary procedures is the wrist pain at the puncture site compared with the femoral approach.

The aim of the study was to evaluate the effect and optimal duration of EMLA cream application in relieving the wrist pain during trans-radial coronary procedures.

# 2. Methods and Materials

### 2.1 Patients

From October, 2003 to March, 2004, consecutive 400 patients scheduled for elective coronary angiogram or coronary percutaneous coronary interventions via the radial artery were included. Patients were excluded if they presented with a

negative Allen test on both wrists, chronic renal failure requiring current dialysis, chronic renal failure that would require dialysis in the future and any known allergy to contrast medium or local anesthetics.

**2.2 Method**

**2.2.1. Study period and randomization**

The study period was divided by 2 phases. Phase 1 study was the initial trial of 147 patients from October, to December, 2003 to evaluate the efficacy and safety of the EMLA cream during the transradial coronary procedures. Phase 2 study was to evaluate the optimal duration of EMLA cream application before the start of the procedure for properly reducing wrist pain in 400cases from October, 2003 to March, 2004.

The sequences of EMLA or placebo application, right or left hand applications and the sequences of radial artery puncture were randomized by a simple randomization table. The subjects and the physician performing radial artery cannulations were blinded as to which hand was treated with placebo or which had EMLA cream applied. The EMLA or placebo cream was applied on the wrist from

2 hour to 4 hour before the procedure in phase 1 study and the duration of drug application was randomized in phase 2 study.

**2.2.2. Application of EMLA or placebo cream and radial artery cannulation**

The experiment investigators provided blinded tubes either with EMLA cream or placebo, which was an odorless white cream that resembled EMLA cream. All EMLA cream and placebo administrations were applied and covered with a transparent dressing measuring 5 cm. The amount of EMLA or placebo cream contained and used in a tube was 2.5 g, the standard adult dose. Each subject that received both placebo and EMLA cream expected a radial cannulation to be done at 2 cm above the styloid process of radius by internship medical doctors (Fig. 1).

Patients were not premedicated beforehand and they were injected at the time of the procedure with 0.6 mL of lidocaine using a 24-gauze needle at expected puncture site of wrist. Radial artery cannulation was performed using 20 G-catheter needle (Sindonbang Co., Korea), and a 5, 6 or 7 Fr arterial sheath (Terumo Co, Japan) was inserted.

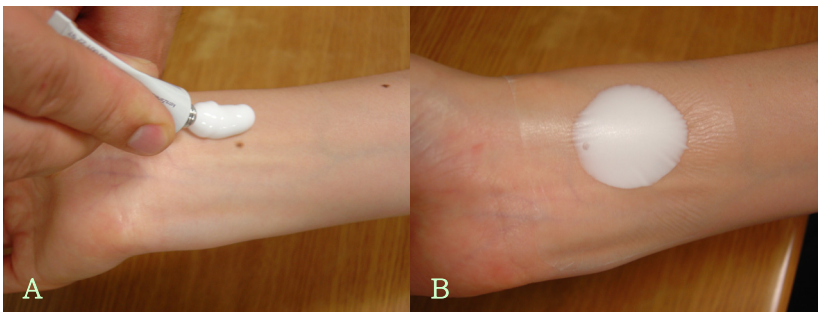


Fig.1. Application of EMLA or placebo cream for transradial coronary procedures. After pasting the cream at the site of the cannulation (A), occlusive dressing with transparent covering was applied (B).

**2.2.3. Assessment of EMLA or placebo cream on wrist pain**

Each patient was asked to identify the pain score that they experienced pain on the cream application site immediately after radial cannulation. The pain score was assessed by the visual analogue scale (VAS) and four-category verbal rating scale (VRS-4). [6] On the VAS, the patients indicated their pain intensity by making a mark on a 10 cm long line that include descriptors labeled at each end of the line of pain intensity (e.g., "no pain" to "pain as bad as it could be"). The patient was instructed to regard the VAS as a continuum and to make a mark at the point along the line corresponding to his/her current level of pain. The score was determined by measuring the distance from left end of the line to the patient's mark (Fig. 2).

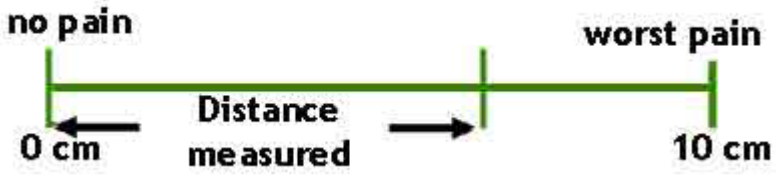


Fig. 2. The pain score was measured by the visual analogue scale (VAS).

Scoring of VRS-4 consists of a finite list of intensity descriptors; 1 point : “ no pain ” , 2 point: “ a little pain ” , 3 point: “ painful, but tolerable ” 4 point : “ Most pain possible ”.

In case of the patients undergoing repeated coronary procedure, we also asked about the patient’s perception of the change in their pain from the last study by percentage change of pain perception.

The primary end point was the subject’s pain that they experienced during the radial cannulation and sheath insertion as assessed by VAS and VRS-4. Secondary end point was the optimal duration of EMLA cream application for relieving the pain without the occurrence of drug adverse reactions.

**2.2.4. Statistics**

Continuous variables are expressed as mean and standard deviation. A 2-tailed

Student's *t* test and ANOVA were used to determine the differences between clinically significant changes in pain among the groups. Discrete variables were compared using simple linear regression tests. A p value $< 0.05$ was considered statistically significant. Statistical analysis was performed using the SPSS 12.0 statistical program (SPSS Inc., Chicago. IL, USA).

# 3. Results

Four hundred consecutive patients were enrolled in this study. Five patients were excluded from the analysis because of incomplete study data.

### 3.1. Phase 1 study for efficacy and safety of EMLA cream application

The clinical characteristics of 147 cases in the control and EMLA group are listed in Table 1. There were no differences in age, gender, procedure time and clinical diagnosis between the two groups.

The wrist pain during lidocaine infiltration and sheath introduction was reduced in the EMLA group more than the placebo as assessed by VAS (control: 49 $\pm$ 24, EMLA: 19 $\pm$ 22, p=0.001) and VRS-4 (control: 2.3 $\pm$ 0.5, EMLA: 1.5 $\pm$ 0.6

p=0.001). There was a significant negative correlation between VAS and the duration of drug application (r = -0.476, p=0.001). The application of EMLA cream marked reduced the pain as expressed by percentage of change compared with the last procedure (control: 130 $\pm$ 45 %, EMLA: 66 $\pm$ 42, p=0.01) in case of repeated trans-radial coronary procedures for follow up angiography.

Table 1. Clinical characteristics and pain scales between the control and EMLA group in phase 1 study

| | Control (n=73) | EMLA (n=69) | p |
|---|---|---|---|
| Age (yr) | 61±11 | 60±10 | 0.72 |
| Sex (male %) | 41 (56) | 37 (54) | 0.52 |
| Diagnosis (%) | | | 0.71 |
| SA | 25 (34) | 24 (34) | |
| UA | 21 (29) | 19 (27) | |
| AMI | 6 (8) | 5 (7) | |
| Others | 20 (27) | 21 (30) | |
| Puncture site | | | 0.82 |
| Right arm | 29(40) | 28(41) | |
| Left arm | 44(60) | 41(59) | |
| ADR | 0 | 2 | 0.60 |
| VAS | 49 ± 24 | 19 ± 22** | 0.001 |
| VRS-4 | 2.3 ± 0.5 | 1.5 ± 0.6** | 0.001 |
| % change of pain in RP | 135 ± 45 | 60 ± 41** | 0.01 |
| No of needle application | 1.9 ± 1.7 | 1.4 ± 0.8* | 0.03 |

*: $p < 0.05$ compare to control, **: $p < 0.01$ compare to control, SA: stable angina, UA: unstable angina, AMI: acute myocardial infarction, ADR: adverse-drug reaction, VAS: visual analogue scale, VRS-4: four-category verbal rating scale, RP: repeated procedure

**2. Phase 2 study for determining the optimal duration of EMLA application**

The baseline clinical characteristics of 395 cases in the control and EMLA groups according to the application time were listed in Table 2. There were no statistical differences in age, sex, procedure site and clinical diagnosis among the groups.

There was a significant difference in the pain score between the control and $EMLA_{1\text{-}2\ hour}$ group as determined by VAS (control: 49$\pm$ 24, $EMLA_{1\text{-}2\ hour}$: 28 $\pm$ 26) and VRS-4 (control: 2.3$\pm$ 0.5, $EMLA_{1\text{-}2\ hour}$: 1.7 $\pm$ 0.6). However, no significant differences were found in the pain score between the control and $EMLA_{0\text{-}1\ hour}$ group as determined by VAS (control: 49 $\pm$ 29, $EMLA_{0\text{-}1\ hour}$: 39 $\pm$ 27) and VRS-4 (control: 2.2 $\pm$ 0.6, $EMLA_{0\text{-}1\ hour}$: 2.0 $\pm$ 0.6).

There was a significant difference in the VAS between $EMLA_{1\text{-}2\ hour}$ and $EMLA_{>4\ hour}$ group ($EMLA_{1\text{-}2\ hour}$: 32$\pm$ 24, $EMLA_{>4\ hour}$: 28 $\pm$ 26), but there was no difference in the VRS-4 ($EMLA_{1\text{-}2\ hour}$: 1.9 $\pm$ 0.6, $EMLA_{>4\ hour}$: 1.5 $\pm$ 0.5).

There were no major adverse drug reactions with minor local erythema occurred in 12 cases (3.5%) which was frequent in the $EMLA_{3\text{-}4\ hour}$ (6.6%) and $EMLA_{>4\ hour}$ (11.9%) groups.

Table 2 Clinical characteristics and pain score as the duration of EMLA cream application in phase 2 study

| | Control (n=98) | EMLA 0-1 hour (n=48) | EMLA 1-2 hour (n=73) | EMLA 2-3 hour (n=72) | EMLA 3-4 hour (n=45) | EMLA > 4hour (n=59) |
|---|---|---|---|---|---|---|
| Age | 60±10 | 57±9 | 58±10 | 60±9 | 61±9 | 62±9 |
| Sex (male %) | 58 (59) | 24 (50) | 41 (56) | 39 (54) | 30 (67) | 31 (53) |
| Diagnosis | | | | | | |
| SA | 31 (32) | 21 (44) | 23 (32) | 24 (33) | 17 (37) | 16 (27) |
| UA | 33 (34) | 10 (21) | 25 (34) | 26 (36) | 17 (37) | 30 (50) |
| AMI | 8 (8) | 2 (4) | 4 (5) | 4 (5) | 4 (9) | 4 (6) |
| Others | 26 (26) | 15 (31) | 21 (29) | 18 (25) | 7 (16) | 9 (15) |
| VAS | 49±29 | 39±27 | 32±24* | 25±23* | 19±19** | 14±18**+ |
| VRS-4 | 2.2±0.6 | 2.0±0.6 | 1.9±0.6** | 1.8±0.5** | 1.6±0.5** | 1.5±0.5** |
| ADR | 0 | 0 (0) | 1 (1.4) | 1 (1.4) | 3 (6.6) * | 7 (11.9) * |
| Procedure Site | | | | | | |
| Rt arm | 40 (40) | 11 (45) | 24 (33) | 28 (39) | 18 (40) | 28 (49) |
| Lt arm | 58 (59) | 27 (55) | 49 (67) | 44 (61) | 27 (60) | 30 (50) |

*: $p < 0.05$ compare to control, **: $p < 0.01$ compare to control, +: $p < 0.01$ compare to $EMLA_{1\text{-}2\ hour}$, SA: stable angina, UA: unstable angina, AMI: acute myocardial infarction, ADR: adverse-drug reaction, VAS: visual analogue scale, VRS-4: four-category verbal rating scale

## 4. Discussion

Radial artery cannulation for transradial coronary procedures is a painful procedure and the standard method of providing analgesia is infiltration of the skin and subcutaneous tissue with lidocaine or prilocaine using a small gauge needle.[7] In our study, we demonstrated that the application of EMLA cream was effective in reducing the wrist pain during transradial coronary procedures and the skin analgesic effect was time-dependant.

The EMLA cream is an oil-water emulsion of lidocaine and prilocaine. Eutectic means that the crystalline bases are mixed to lower the melting point. Therefore, it is possible to create an ideal preparation for skin penetration.[8] Topical EMLA cream allows the anesthetics to hinder initiation and conduction of nerve impulses. So, it is widely used for a variety of painful cutaneous procedures. [1-3] Several studies have reported EMLA cream to be superior to lidocaine infiltration in providing analgesia for radial artery cannulation for pressure monitoring.[3] Despite these usefulness of EMLA cream, it is not widely used in standard clinical practice because the optimal duration to drug application is unknown, and different results

reported for efficacy depending on the procedures it is used for. Lander et al. determined that factors predicting success of EMLA were the type of procedure, duration of drug application and patient's anxiety.[9]

It is essential to determine the optimal duration of EMLA application depending on the procedure. Joly et al. reported that EMLA cream was superior to lidocaine local infiltration in a study with 500 patients in which the cream was applied 2 h prior to cannulation [3]. In that report, EMLA was applied for a fixed duration (2 hour) before the procedure. So, the range of optimal duration for cream application was not determined.

The early studies from the 1980s and manufacturers have suggested that applying EMLA cream for 60 minutes is necessary to provide sufficient analgesia.[1,2] Bjerring et al [10] shown that a 60-min application is insufficient to produce effective anesthesia because the depth of dermal anesthesia is approximately 5 mm after 90 min. So, a 2-h interval was suggested to optimize anesthesia effectiveness. Russell et al.[11] randomized 60 patients to receive EMLA cream for 60 or 90 min before radial artery cannulation for pressure monitoring, or

the patients received 2% lidocaine infiltration. Most of the patients in the 90-min EMLA group experienced no pain or mild pain and the difference was statistically significant compared with the two other application groups. This study suggested that a 90 min application prior to radial cannulation is the optimal duration for procedure.

However, these data were inconclusive due to the small number of patients in the study and the different procedures types that were preformed after the EMLA application. So, it is difficult for us to extrapolate these data to the transradial coronary procedures.

In real practice, it is impossible to apply the EMLA cream for a fixed time prior to the procedure due to various reasons including time delays for the prior procedures, ad hoc procedures or emergency procedures. Thus, it is necessary to determine the range of time interval from the application of the cream necessary prior to the start of procedure that is sufficient to reduce the wrist pain.

In this study, we documented that a period less than 1 hour prior to the start of the procedure was insufficient to reduce the wrist pain and application of EMLA

cream more than 3 hours prior to procedures was relation to increase erythematous complications at the application site. Therefore, EMLA cream was able to reduce the wrist pain during arterial cannulation for transradial coronary procedures when the application time is between 1 hour to 3 hour before the start of procedures.

# V. Conclusions

This study was a randomized and controlled study to compare topical analgesic cream versus local infiltration for radial artery cannulation and sheath insertion. The aim of the study was to evaluate the effect and optimal duration of drug application of a eutectic mixture of local anesthetic (EMLA) cream in relieving the wrist pain during transradial coronary procedures. The important findings are as below.

1. The pain was less severe in the EMLA group than the placebo group as measured by VAS (control: 49 $\pm$ 24, EMLA: 19 $\pm$ 22, p=0.001) and VRS-4 (control: 2.3 $\pm$ 0.5, EMLA: 1.5 $\pm$ 0.6 p=0.001). There was a significant negative correlation between the VAS and the duration of EMLA application(r = -0.476, p=0.001).

2. There was a significant difference in the pain score between the control and $EMLA_{1\text{-}2\ hour}$ group as measured by VAS (control: 49 $\pm$ 24, $EMLA_{1\text{-}2\ hour}$: 28 $\pm$ 26) and VRS-4 (control: 2.3 $\pm$ 0.5, $EMLA_{1\text{-}2\ hour}$: 1.7 $\pm$ 0.6). However, no significant differences were present in the pain score between the control and $EMLA_{0\text{-}1\ hour}$

group as measured by VAS (control: 49 $\pm$ 29, EMLA $_{0\text{-}1\ hour}$: 39 $\pm$ 27) and VRS-4 (control: 2.2 $\pm$ 0.6, EMLA$_{0\text{-}1\ hour}$: 2.0 $\pm$ 0.6).

3. Drug induce local erythema occurred in 12 cases (3.5%) which was frequent in the group of EMLA $_{3\text{-}4\ hour}$ (6.6 %) and EMLA $_{>4\ hour}$ (11.9%).

In conclusion, EMLA cream can be effective in reducing the wrist pain without significant drug-related complications during arterial cannulation of transradial procedures, when the application time is 1 to 3 hour before the start of procedures.

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## 국문 요약

# 요골 동맥을 이용한 관동맥 시술시 EMLA크림이 손목 천자부위의 통증 감소에 미치는 효과

< 지도 윤 정 한 교 수 >

연세대학교 대학원 의학과

김 장 영

요골동맥을 통한 관동맥 조영술 및 중재술시 요골동맥의 삽관 시 환자에게 통증을 유발한다. 이를 최소화하기 위하여 표준적으로 사용되는 방법은 적은 구경의 바늘을 이용하여 리도카인과 같은 국소 마취제를 피부 및 피부 하 조직에 주입한 후 시술을 시행하고 있으나 이런 방법도 통증을 유발한다. EMLA크림은 2.5% 리도카인과 2.5% 프릴로카인이 혼합되어 있는 국소 마취제로, 피부의 간단한 시술시 통증을 줄여 줄 수 있는 도포용 국소 마취제이다. 본 연구의 목적은 요골 동맥을 이용한 관동맥 시술시 EMLA크림이 손목 천자부위의 통증

감소에 미치는 영향과 연고 도포의 적정 시간에 관해 알아보고자 하였다.

관동맥 조영술 및 중재술을 시행 받는 연속적인 400명을 대상으로 전향적, 이중맹검, 무작위 배정을 통하여 양측 손목에 EMLA크림 및 위약을 도포한 후 천자 부위의 통증 정도를 비교 하였다. 또한 EMLA크림의 통증 역치 및 국소 합병증을 평가하고자 도포 시간을 무작위로 시술 전 0-1시간, 1-2 시간, 2-3 시간, 3-4시간, 4시간이상으로 나누어 도포하였다. 표준화된 통증 측정 방법인 visual analogue scale(VAS) 및 four-category verbal rating scale(VRS-4)을 통하여 평가 하여 다음과 같은 결과를 얻었다.

1. VAS는 위약군이 49 $\pm$ 24이며 EMLA군이 19 $\pm$ 22로 유의한 차이가 있었고 (p=0.001), VRS-4는 위약군이 2.3 $\pm$ 0.5이며 EMLA군이 1.5 $\pm$ 0.6로 유의한 (p=0.001) 차이가 있었으며, 위약군에 비해 EMLA군이 요골동맥 삽관 시 통증을 유의하게 줄였다. 또한 EMLA 도포시간과 VAS 통증의 정도는 음의 상관관계가 있었다(r = -0.476, p=0.001).
2. 도포시간에 따른 0-1시간에 도포된 EMLA군이 VAS는 39 $\pm$ 27, VRS-

4는 2.0 ± 0.6로 위약군에 비해 유의한 차이가 없었으나 ($p>0.05$), 1-2시간에 도포된 EMLA군이 VAS는 28 ± 26, VRS-4는 1.7 ± 0.6로 위약군에 비해 유의하게 천자 부위 통증을 경감 하였다($p<0.01$).

3. 약물에 의한 국소 발적은 3-4시간에 도포된 EMLA군에서 6.6%, 4시간 이상 도포된 EMLA군에서 11.9%로 위약군에 비해 유의하게 증가하였다($p<0.01$).

이상의 결과로 관동맥 요골 동맥을 이용한 관동맥 시술시 EMLA크림이 손목 천자부위의 통증을 유의하게 감소시켰으며, 시술 전 1-3시간에 도포된 EMLA크림이 국소 합병증이 없이 통증을 유의하게 감소 시킬 수 있는 연고 도포의 적정 시간이다.

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핵심 되는 말: 국소 마취제, 요골동맥 삽관, EMLA크림