Does a Lidocaine Patch Reduce the Pain at Venous Cannulation in Adults?

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In this study we evaluated whether a lidocaine patch reduces the pain relating to a venous cannulation in adults. The patch is consisted of the base containing 50% lidocaine on a thin polyester membrane. Its surface area is 15 cm^2. Twenty-six adult patients scheduled for elective surgery (11 males and 15 females) were randomly divided into two groups according to application periods: Group A for 15 min and Group B for 30 min. Either the dorsal part of the hand or the radial side of the wrist was chosen and covered with the patch. Pain assessment was made by patients using a 0–100 point visual analog scale (VAS). In 7 patients of Group A, plasma lidocaine levels were measured 15 min after application by homogeneous enzyme immunoassay. The levels were further measured 30 and 60 min after application in 3 of those patients. The mean VAS score was 28.4 ± 13.1 (mean ± SD) for Group A and 51.8 ± 15.9 for Group B, and the difference was statistically significant ($P < 0.05$). Plasma lidocaine levels were always below 0.2 $\mu g \cdot ml^{-1}$. The results indicate that the skin was partially anesthetized by the lidocaine patch. A lidocaine patch may be useful and safely applicable for venous cannulation in adult patients. (Key words: adult, lidocaine patch, venous cannulation)

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Almost all patients scheduled for surgery have been suffered from pain associated with various anesthetic procedures. A venous cannulation is also a painful procedure that may cause fear and anxicty even in adult patients. Many attemps such as topical uses of EMLA (eutectic mixture of local anesthetics) cream have been tried to alleviate this pain[1–3]. Although the application of EMLA cream is a convinient method, it is not commercialy available in Japan. In this study we evaluated the clinical usefulness of a lidocaine patch for venous cannulation in adult surgical patients.

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Methods

With approval from Institutional Human Ethics Committee, 26 patients undergoing elective surgery and subjected to insertion of an intravenous cannula were equally and randomly divided into two groups by application periods (table 1). Informed consent was obtained from each patient at the

Table 1. Characteristics of patients in each group

	Male	Female	Cannulation Site Wrist	Hand	Age (yr)	Weight (kg)	Height (cm)
Group A	6	6	5	7	45.3 ± 8.00	59.1 ± 6.64	159.8 ± 6.03
Group B	5	9	5	9	38.1 ± 8.76*	60.2 ± 12.2	161.0 ± 8.10

Values for age, weight, and height are expressed as mean ± SD.
*statistically significant compared with Group A, $P < 0.05$

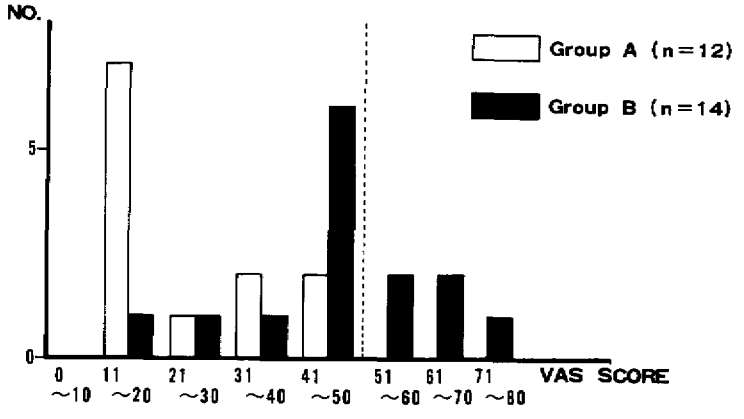

Fig.

time of preanesthetic visit. No patients were recieved premedication of analgesics and sedatives. A venous cannulation was performed either 15 min (Group A) or 30 min (Group B) after patch application.

The patch we used in this study was a prototype made of the base containing lidocaine on a piece of thin polyester film (Lederle Japan). Its surface area and thickness is 15 cm^2 (3 cm × 5 cm), 70 μm (film 50 μm, base 20 μm), respectively. It contains 15 mg of lidocaine (500 $mg \cdot ml^{-1}$, 50 vol%) per patch.

We chose either an vein at the dorsal part of the hand or the cephalic vein at the wrist for the venous puncture because these sites are commonly used in clinical practice. The patch was applied after the skin was wiped dry. When the patch was removed, the skin was observed for any local reaction including redness, paleness, or edema and wiped with 70% alcohol sponges. The venous puncture was then performed with a 16 or an 18 gauge cannula by one board-certified experienced anesthesiologist.

A 0–100 point visual analog scale (VAS) in which the left end, point 0 means painless and the right end, point 100 means intolerant pain was shown in front of the patient. Soon after the puncture, the patient was asked for the pain score when the cannula cut into the vein. In 7 patients of Group A, we measured the arterial plasma concentrations of lidocaine by homogeneous enzyme immunoassay (EMIT; EMIT-cad, lidocaine assay, Syva, Palo Alto, CA, USA) 15 min after patch application. The further measurements were made 30 and 60 min after patch application in 3 of those patients.

VAS score under 50 was defined to be effective. Values were expressed by mean ± SD. Statistical analysis was performed by t test, and $P < 0.05$ was considered significant.

Results

The patient of Group B is younger than that of Group A, and the mean height and weight were similar between two groups (table 1).

The total number of the patients at each VAS score is shown in figure. The score by VAS was 28.4 ± 13.1 for Group A, and 51.8 ± 15.9 for Group B, and the difference was statistically significant ($P < 0.05$). All people in Group A and 64% in Group B were deemed effective.

The adverse effects were erythema detected in two patients of each group. There were no other skin reactions due to patch application such as redness, paleness, and edema.

Arterial plasma levels of lidocaine for 15, 30, 60 min after application were all below 0.5 $\mu g \cdot ml^{-1}$.

Discussion

Anesthesiologists are facing the discrepancy that painful procedure such as infiltration of local anesthetics is needed to remove the pain associated with anesthesia. It would be convenient to alleviate the pain with no kind of pain. In this study, the efficacy of a lidocaine patch was satisfactory to use in the operating room because not only it is painless but it expresses the effect quickly and safely.

We chose adult patients undergoing elective surgery and they might have the comprehension and acceptance for various kinds of pain. If the subjects were children or the patients were not to be scheduled for surgery, the pain score might be higher than our results.

The size of film is 15 cm^2 and the radial side of the wrist or the dorsal part of the hand is covered with a patch. Accordingly, there must be at least one vein under that area and there may be four or five veins suitable for venous cannulation. However, it is rather too large for children or small patients. The polyester film makes the base attach to the epidermis tightly and it may contribute to promote the permiation.

Because lidocaine was detected in plasma samples from systemic circulation, the lidocaine contained in the patch should have past through the skin. The stratum corneum is thought to play an important role against permiation of many chemical substances[4,5]. Removal of the layer by scratching may also improve the permiability of the drug.

Our results showed that in 80.1% of all patients a lidocaine patch seemed to be effective, although there was no placebo group in this study. It was not expected that the efficacy of the patch would be greater in Group A (application for 15 min) than in Group B (for 30 min). The reason is not clear but lidocaine in the patch may pass the dermis, which includes many terminals of sensory fibers, more rapidly than we expected.

An adverse effect is only erythema in two patients of each group. It is essential for safer and routine use of the patch not to cause frequent unpleasant reactions. Of course, we must use the patch carefully, in particular, for the patients who have allergic property.

Plasma lidocaine levels were always far below the toxic range. It is probably because the total amount of lidocaine is small (15 mg per patch).

We studied the efficacy of the new preparation of lidocaine patch. The quick and safe expression of analgesic effect may make wide use of the patch possible. However, we need a further evaluation for the routine use of this patch and in particular for the application to the children.

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