Lidocaine tape relieves pain due to needle insertion during stellate ganglion block

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Purpose: To investigate the efficacy of lidocaine tape, a new preparation of lidocaine for cutaneous topical anaesthesia in the form of a self-adhesive tape, in alleviating the pain of needle insertion during stellate ganglion block.

Methods: In a double-blind, placebo controlled study, 30 adult outpatients undergoing stellate ganglion block were allocated to receive all of the following five treatments in random order: placebo tape applied to the intended site of the block (control), or lidocaine tape applied for 7, 15, 30, and 60 min. After the block was performed using a 24-gauge needle, the pain associated with needle insertion was assessed using a visual analogue scale (10 cm VAS) and the four-point verbal rating score (VRS 0–3).

Results: With placebo tape, the VAS and VRS scores were 2.4 ± 1.27 (0.5–4.8) (mean $\pm$ SD (range)) and 1.5 (1–2) (mean (range)), respectively. The pain scores were reduced ($P < 0.01$) by lidocaine tape after application for 7 min (1.6 ± 1.06 and 1.0 (0–2) for VAS (mean $\pm$ SD) and VRS (mean (range)), respectively), 15 min (1.5 ± 1.00 and 1.0 (1–2)), 30 min (1.5 ± 1.08 and 1.0 (1)), and 60 min (0.6 ± 0.70 and 0.6 (0–1)). Skin erythema was more frequent with lidocaine tape than with placebo tape (seven minutes of lidocaine tape vs placebo tape, $P < 0.05$; 15, 30, and 60 min of lidocaine tape vs placebo, $P < 0.0005$).

Conclusion: Stellate ganglion block without analgesia is fairly painful in some patients, even when using a 24-gauge needle, and needle pain is reduced by lidocaine tape after an application time of seven minutes or more.

Objectif : Vérifier l'efficacité d'un ruban adhésif lidocaïné, une nouvelle préparation anesthésique cutanée de surface destinée à soulager la douleur provoquée par l'introduction de l'aiguille au moment de la réalisation du bloc stellaire.

Méthodes : Au cours d'une étude à double insu avec contrôle par placebo, 30 adultes programmés pour un bloc stellaire recevaient aléatoirement une des cinq modalités suivantes : l'application, au site du bloc, de l'adhésif placebo (contrôle) ou de l'adhésif lidocaïné pendant 7, 15, 30 ou 60 min. Une fois le bloc effectué avec une aiguille 24 G, la douleur provoquée par l'introduction de l'aiguille était évaluée sur une échelle visuelle analogique (ÉVA de 10 cm) et sur une échelle d'évaluation verbale simple à quatre niveaux (EVS 0–3).

Résultats : Avec le placebo, les scores sur l'ÉVA et l'ÉVS étaient respectivement de $2,4 \pm 1,27$ (0,5–4,8) (moyenne $\pm$ ET (écart)). Les scores de douleur diminuaient ($P < 0,01$) avec le ruban lidocaïné appliqué pendant 7 min ($1,6 \pm 1,06$) et 1,0 (0–2) sur l'ÉVA (moyenne $\pm$ ET) et l'ÉVS (moyenne(étendue)), respectivement, 15 min ($1,5 \pm 1,00$ et 1,0 (1–2)), 30 min ($1,5 \pm 1,08$ et 1,0 (1)), et 60 min ($0,6 \pm 0,70$ et 0,6 (0–1)). L'érythème cutané était plus fréquent avec le ruban lidocaïné qu'avec le ruban placebo (sept minutes de ruban lidocaïné vs ruban placebo, $P < 0,05$; 15, 30 et 60 min de ruban à la lidocaïne vs placebo, $P < 0,0005$).

Conclusion : Sans analgésie préalable, le bloc stellaire peut être douloureux chez certains patients, même avec une aiguille 24G, et cette douleur peut être diminuée par un ruban lidocaïné appliqué pendant sept minutes ou plus.

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LIDOCAINE tape (Penles,[®] Japan Lederle, Tokyo, Japan) (Figure 1) is a new preparation of lidocaine in the form of a self-adhesive tape for cutaneous topical anaesthesia.^{1,2} The tape (30.5 × 50.0 mm) is transparent and consists of a thin film backing with a lidocaine-containing hypoallergenic polymer adhesive. After peeling the liner from the tape, the adhesive surface of the tape is applied to the skin. The polymer adhesive contains a crystalline base form of lidocaine (18 mg per 12 mg polymer) at a concentration of 60%. This high concentration of lidocaine promotes skin penetration. Local irritation, due to the drug, may not be a problem because of controlled release from the polymer matrix. The backing film serves as an occlusive dressing, promoting further penetration of the anaesthetic through intact skin. Since one unit of the tape contains only 18 mg lidocaine, the plasma concentration of the drug would be expected to be very low even after prolonged application. Its topical analgesic properties during venepuncture and its freedom from systemic toxicity have been confirmed.^{1,2}

Stellate ganglion block is used primarily in the treatment of upper extremity sympathetic dystrophy, vascular insufficiency, and other chronic pain conditions.³⁻⁷ Alleviating pain associated with needle insertion for the block is desirable for reducing the patient's distress as well as minimizing unintentional patient's movement.

The aim of the present study was to investigate the efficacy of lidocaine tape for alleviating the pain of stellate ganglion block.

Methods

After obtaining Hospital Ethics Committee approval and written informed consent, we studied 30 adult outpatients who were scheduled to receive a series of stellate ganglion blocks (at least once a week for total of minimum five blocks) at our pain clinic. Patients with diabetes mellitus, allergy to amide local anaesthetics, skin lesions or disordered sensation at the site of needle insertion, those on analgesic therapy, and those who could not understand the concept of the visual analogue scale (VAS) were excluded.

Each patient was allocated to receive all of the following five treatments in random order: placebo tape (Tegaderm, 3M, Canada) 30.5 × 50.0 mm applied to the site of the block (control); lidocaine tape applied for seven minutes; lidocaine tape applied for 15 min; lidocaine tape applied for 30 min; and lidocaine tape applied for 60 min. We limited the duration of application to 60 min, because our aim was to alleviate pain in an outpatient setting within an acceptable time. The application time of the placebo tape was at least seven minutes and no more than 60 min. Lidocaine or place-

FIGURE 1 Lidocaine tape

Upper: user part from below. Half of the liner is removed. Lower: cross section of the tape with liner. The tape consists of a thin film backing with a lidocaine-containing hypoallergenic polymer adhesive. The liner has a slit to facilitate peeling.

bo tape was applied to the skin exactly over the intended block site by a well-trained pain clinic nurse. After the designated time, the tape was removed and the skin was disinfected with alcohol by the nurse. Then the operator was called, and commenced the block within one minute after tape removal. All stellate ganglion blocks were done by one of the investigators (SK) with the patient in the supine position using an anterior paratracheal approach. A 24-gauge 3.2-cm needle (JMS, Hiroshima, Japan) was advanced to the base of the transverse process of the C7 vertebra and 6 ml mepivacaine 1% were injected. To discriminate injection pain or discomfort (if present) from pain associated with needle insertion, five seconds were allowed to elapse before injection of the local anaesthetic. After the procedure, each patient completed a 10 cm VAS and four-point verbal rating score (VRS) (0 = no pain; 1 = mild pain; 2 = moderate pain; 3 = severe pain) to quantify the pain associated with needle insertion. The operator was blinded to both the type of tape and the application time. Any complications before and after the block, including skin erythema or itching, or the presence of hoarseness were noted.

Data are presented as the mean $\pm$ SD or mean (range). The VAS and VRS data were tested using Friedman's analysis of variance followed by the Student-Newman-Keuls test. Correlation analysis was performed using Spearman's rank correlations. The Mann Whitney *U*-test was used to compare differences in VAS and VRS scores between the sexes. The incidence of side effects was analyzed by Fisher's exact probability test with Bonferroni's correction. A probability value less than 0.05 was considered statistically significant.

Results

The age of the patients was 52 ± 15 yr, and there were 17 women and 13 men. The VAS and VRS scores obtained with the placebo tape were 2.4 ± 1.27 (range: 0.5–4.8) and 1.5 (1–2), respectively. These pain scores were reduced ($P < 0.01$) by the lidocaine tape after 7, 15, 30, or 60 min of application (Figure 2). There were no differences in VAS or VRS scores between the sexes

at any time. No correlation was noted between age and the VAS or VRS scores.

Skin erythema was observed more frequently at the site of application with lidocaine tape than with placebo tape (17% after placebo tape; 50% after lidocaine tape for seven minutes ($P < 0.05$ vs placebo); and 67%, 83%, and 73% after 15, 30, and 60 min, respectively ($P < 0.0005$ vs placebo). The skin reaction was non-pruritic and resolved within 30 min of tape removal in all patients. No other skin lesions were detected. Hoarseness or signs of stellate ganglion block such as Horner's syndrome, injection of the conjunctiva, or nasal stuffiness³⁻⁵ were not detected in any of the patients before the block. No patient complained of signs of lidocaine central nervous system toxicity (drowsiness, perioral numbness, or lightheadedness)⁵ before the block. After the block, some patients became hoarse (one patient each after lidocaine tape for 7 and 60 min, and two patients after lidocaine tape for 15 min) but the incidence of this complication was not statistically different among each treatment. After the block following lidocaine tape application for seven minutes, one patient developed ecchymosis at the block site. This patient had no history of abnormal haemostasis. There were no serious side effects of the procedure in any patient.

Discussion

In the present study, the VAS and VRS scores revealed that stellate ganglion block was fairly painful for some patients without analgesia, even when a 24-gauge needle was used, and that lidocaine tape reduced the pain after an application time as short as seven minutes. The tape may therefore serve to increase patient comfort and promote the acceptability of block procedures. This may be especially true when a series of blocks is planned, because accumulation of painful experiences may lead to intolerance. We recommend an application time of 60 min, because the quality of anaesthesia was better at 60 min than at 30 min. After application for 60 min, 11 of 30 patients (37%) did not perceive pain on needle insertion (VRS = 0), whereas all patients still experienced some pain at 30 min. Providing skin anaesthesia may minimize unintentional movement of the patient upon needle insertion and may ensure relaxation of the neck muscles, thus increasing safety because the needle insertion site is close to several major neural and vascular structures.³⁻⁵

Erythema was more frequent after use of the lidocaine tape than after placebo tape. This may be due to lidocaine-induced local hyperaemia.^{8,9} With lidocaine tape, hoarseness as well as signs of stellate ganglion block were not observed before the block procedure. Therefore, the depth of tissue penetration with an

FIGURE 2 Visual analogue scale

(VAS: 10 cm VAS) and four-point verbal rating score (VRS: 0 = no pain; 1 = mild pain; 2 = moderate pain; 3 = severe pain) data obtained after needle insertion for stellate ganglion block with application of placebo tape and lidocaine tape (7 min, 15 min, 30 min, or 60 min). Individual (■) and mean VAS (□) and VRS (○) scores are shown.

* $P < 0.01$ vs placebo tape. # $P < 0.05$, † $P < 0.01$ vs application of lidocaine tape for 60 min.

application time of up to 60 min was sufficient to reduce pain but not deep enough to affect either the stellate ganglion or the recurrent laryngeal nerve. After the block, one patient developed ecchymosis. We assume that the vasodilatory effect of lidocaine^{8,9} may have contributed to this because dilated vessels may be more vulnerable to injury by the needle used for the block. However, the frequency of ecchymosis (one of 120 blocks performed after lidocaine tape application) was too low to confirm a role of the tape in this complication.

In conclusion, we demonstrated the efficacy of a transdermal topical anaesthetic preparation, lidocaine tape, for alleviating pain during stellate ganglion block. Pain relief was evident after an application time as short as seven minutes.

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