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Mitigation of injection-induced pain using 10% lidocaine spray: An observational study with cancer patients

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Abstract

Objectives: To observe the effectiveness of dermal application of 10% lidocaine spray that is commonly used for diagnostic gastrointestinal intubation in mitigating injection-induced pain in cancer patients.

Methods: The study was carried out with cancer patients who needed at least two injections for either hematological analysis (cubital vein) or administer chemotherapy (dorsal metacarpal vein). During the first procedure the injection was performed as per the procedure (without the spray of 10% lidocaine), while during the second before the injection, lidocaine was sprayed and then the injection procedure was performed using a 22 gauge needle. Pain assessment was done on both occasions on a four point verbal rating scale (none = 0, mild pain = 1, moderate pain = 2, severe pain = 3 and extreme pain = 4). The difference in the response between the two points were tabulated and subjected to paired "t" test statistical analysis.

Results: The results indicate that spraying of 10% lidocaine significantly ($p < 0.0001$) decreases the pain in cohorts was median cubital vein or dorsal metacarpal veins were punctured. The most important observation was that lidocaine reduced the pain by 70.5% when median cubital vein as against the 51.20% reduction observed when dorsal metacarpal vein was involved.

Conclusions: Lidocaine 10% spray was effective in reducing the injection.

Keywords: Pain management; anesthetics, topical, lidocaine, xylocaine, lignocaine, venipuncture, cancer

Introduction

Pain, which is termed by the International Association for the Study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" [1] is a neglected, public global health issue [2]. Literature study suggests that most people have serious concerns with intravenous injections and are highly anxious with the thought and during the injection procedure [3]. At times, in worse conditions an individual may also develop anxiety related reactions like hypotension, vasovagal shock and unconsciousness, all of which may cause anxious moments for the patient caregivers and the healthcare personnel [3].

With respect to cancer patients, reports indicate that both acute and chronic pain continues to be one of the major issues and the fact that they have a reduced pain threshold (tolerance for pain) complicates medical care especially when phlebotomy is required [4,5]. Realistic appraisals are that nearly 70% of cancer patients develop cancer related pain during the course of their illness and also that in most of these individuals complete mitigation of pain is elusive [4,5]. In cancer diagnosis and treatment the withdrawal of blood and administering therapeutic drugs (like anticancer drugs, antibiotics etc), which at times are to be done on a regular basis is unpleasant for the patient. In lieu of these observations it is apparent that pain mitigation means are to be adopted for better psychological and treatment compliance and, treatment and diagnostic follow-ups.

Topical analgesics have probably been around for as long as medicine itself and evidence from the Chinese medical texts found in a tomb dated back to 186 BC have documented that certain herbs were topically applied to mitigate and afford pain relief [6]. Local anesthesia

mediates sensory loss by reversibly blocking the nerve conduction by stabilize neuronal membranes and inhibiting the ionic fluxes required for the transmission of neural impulses [6]. In recent times lidocaine [2-(diethylamino) -N-(2,6-dimethyl phenyl) -acetamide] an amide-type anesthetic mediating its analgesic effect by decreasing the voltage gated sodium-channel activation and blocking generation of action potential has been of wide use [7]. Mechanistic studies have shown that the topical application of lidocaine reduces neuropathic pain by selectively blocking the Ad and C fibers sufficient to attenuate pain but leaving normal sensation intact [8].

Previous studies have shown that 10% aerosol spray of lidocaine (also known as xylocaine and lignocaine) is an effective topical aerosol anesthetic and has been approved by Food Drug Administration of USA to be used as an anesthetic for skin or mucosa, especially during procedures like laryngoscopy, bronchoscopy, tonsillectomy and endotracheal intubation [6, 9]. Additionally studies have also shown that lignocaine was a better analgesic than either ethyl chloride or nitrous oxide for peripheral intravenous cannulation [10]. In lieu of all these reports the present study was conducted to ascertain whether topical application of 10% aerosol spray of lidocaine commonly used for diagnostic gastrointestinal intubation would be effective in decreasing the incidence and degree of pain incurred during venipuncture (for hematological and biochemical analysis) and cannulation (during administration of chemotherapy) in adult cancer patients

Materials and Methods

Patients and Methods

This was a prospective, single blind, observational study and was carried out between January 2016 to March 2016 in the clinical laboratory and Medical Oncology departments of Mangalore Institute of Oncology, Pumpwell, Mangalore. The study was initiated and carried out after obtaining the approval of the institute's ethics committee and in agreement to the guidelines of Helsinki declaration for research with humans. During the study period, a senior attending nurse approached eligible volunteers and their care takers, and informed them about the study objective. They were also informed that their participation was voluntary and that this will not affect their proposed treatment. A written informed consent was taken from the willing volunteer.

The inclusion criteria included subjects diagnosed with cancer above the age of 18, literate to the level of understanding the study objective and requiring at least two venipuncture (either for hematological assays or for administering chemotherapy). The exclusion criteria included patients who were in a comatose or terminally ill state, patients with vascular diseases, habituation to analgesics, sedatives or anti-anxiety drugs, allergic reactions to lidocaine and infection on the dorsum of their arms. Patients with psychological illness like schizophrenia, bipolar, and pregnant women were excluded from the study. No oral analgesics or sedatives were proposed to be given before the venipuncture.

Study grouping/stratification:

The study was stratified in to two broad classifications to understand the efficacy of the topical analgesics. One group consisted of patients where phlebotomy was to be performed

to assess the hematological and biochemical parameters with the whole process being completed in 2 minutes from the median cubital vein. Most of the volunteers in this cohort were undergoing radiotherapy for their cancers. The other group consisted of patients who needed cannulation (dorsal metacarpal veins) for the administration of anticancer drugs and the process extended for more than 60 minutes. Patients who were on chemotherapy were assigned to this group.

Lidocaine spray

The lidocaine solution used for the study was from Neon Laboratories Limited, Andheri, Mumbai.

Procedure

Patients were assessed before and after the lidocaine 10% aerosol spray during venipuncture as well as after the medical procedure by the attending nurses and medical doctors. The site of injection was thoroughly cleaned using an alcohol swab. After occluding the venous drainage using a pneumatic tourniquet on the upper arm, the patient were pretreated with the Lidocaine topical spray over the site and a 22 gauge needle was used to puncture the Median cubital Vein to draw blood. Similarly, for the cancer patients receiving chemotherapy as infusion for extended period, a 22 gauge IV cannula was used to puncture the dorsal metacarpal vein after pretreatment with the lidocaine spray.

The pain assessment was done by the patient after the completion of the procedure using a four point verbal rating scale: None = 0, Mild pain = 1, Moderate pain = 2, severe pain = 3 and extreme pain = 4. In each patient, the verbal pain score was compared before and after using lidocaine spray. Additionally percent differences were also calculated to ascertain the effectiveness in a percentage index for clarity.

Statistical Analysis

Differences in categorical data and continuous data were compared using the paired t test. The data was tabulated for both median cubital and dorsal metacarpal veins by stratifications based on gender. A p value of 0.05 or less was considered significant.

Results

A total of 110 patients with various cancers volunteered for the study (Figure 1). From a gender perspective 44 of the volunteers were women and 66 were men. The results are expressed in mean and standard deviation. In the cohorts where median cubital vein was being used for blood drawl for hematological parameters a marked decrease in the pain was observed after the lidocaine spray in both men and women and was statistically significant ($p < 0.0001$) Table 1. With respect to the reduction in pain when dorsal metacarpal veins used for injecting anticancer drugs a noticeable reduction in the pain was observed after the lidocaine spray in and women ($p = 0.02$; $t = +2.44$) and men ($p = 0.002$; $t = +3.2$). With respect to the degree of effectiveness it was observed that the spray was more useful in mitigating the pain when median cubital vein was involved than the dorsal metacarpal veins and is represented in table 1 and 2.

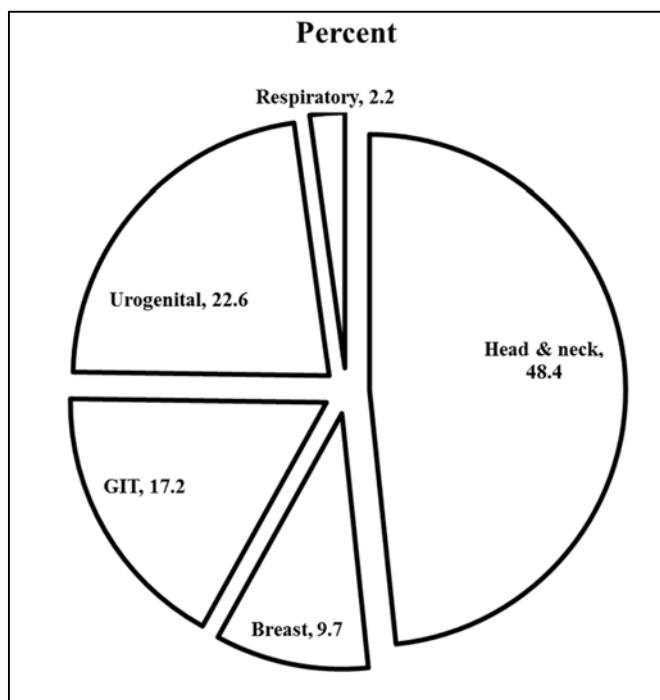


Fig 1: The details of cancer patient population used in the study

Table 1: Details of mitigation of pain when Median cubital vein was injected and 10% lidocaine was used

Median cubital vein	Age	Duration (hrs)	Pain before	Pain after	Percent reduction	
Female (n = 23)	49.00±11.7	1.33±0.47	1.08±0.88	0.30±0.54	72.22222	P = <.0001 t = +5.1
Male (n = 40)	57.21±14.87	1.04±0.20	1.04±0.84	0.31±0.54	70.19231	P = <.0001 t = +5.13
Both (n = 63)	54.66±14.47	1.24±0.43	1.05±0.85	0.31±0.54	70.47619	P = <.0001 t = +6.28

Table 2: Details of mitigation of pain when dorsal metacarpal veins was injected and 10% lidocaine was used

Dorsal metacarpal veins	Age	Duration (hrs)	Pain before	Pain after	Percent reduction	
Female (n = 21)	51.61±11.49	3.14±1.32	1.76±1.15	0.90±1.06	48.86364	P = 0.02 t = +2.44
Male (n = 26)	53.62±12.22	3.7±1.7	1.59±0.95	0.74±0.96	53.45912	P = 0.002 t = 3.2
Both (n = 47)	52.75±11.95	3.45±1.57	1.66±1.04	0.81±1.01	51.20482	P = 0.0001 t = +4.02

Discussion

In the present study it was observed that topical spray of 10% lidocaine was effective in mitigating the pain in cancer patients. Our observations are in agreement to previous reports where studies have shown lidocaine to be effective when administered transdermally in conditions like allodynia, hyperalgesia and continuous pain [11-16]. From an historical view, most of the studies with lidocaine have been with intravenous administration and has been an effective analgesic in clinics [7, 8].

With regard to lidocaine’s efficacy through transdermal delivery research indicate it to be effective in mitigating complex regional pain syndrome type 1 [13] refractory pain associated with sickle cell vaso-occlusive crisis [15], spinal puncture [17], burns [16, 18]; post-herpetic neuralgia [19]; diabetic polyneuropathy [20]; myofascial pain [21]; low-back pain [22, 23]; neuropathic Pain in people with osteoarthritis [24]; wound pain in gynecologic laparoscopic surgery [25]. Additionally studies have also shown that in people with pain due to burns, post use of lidocaine patches improved mobility and activity levels, improved sleep, and the ability to touch the area of their original burn without pain [26].

As far as the authors are aware of this is the first study to observe the efficacy of 10% lidocaine spray, a commonly used analgesic to decrease discomfort or pain during medical procedures/exams (e.g., sigmoidoscopy, cystoscopy). However lidocaine patches have been previously studied for its usefulness in mitigating pain caused by needle sticks. Observations by Hersh and co workers [27] have shown that Lidocaine patches were effective in reducing the pain experienced after insertions of a 25-gauge needle. Detail analysis showed that lidocaine patches offered better analgesia than the placebo within 2.5 to five minutes after placement and was safe in reducing needle insertion pain [27]. Additionally studies have also shown that 5 % lidocaine patches were effective in reducing painful scars (post-thoracotomy and post-mastectomy) and pain caused by chest wall tumors, and to be an effective short-term co-analgesic in cancer pain with opioids [28]. The observations that the lidocaine spray is effective in mitigating injection pain in cancer patients have a lot of application. The 10% lidocaine spray is FDA approved and is commonly used during medical procedures. The other important aspects that makes transdermal lidocaine useful are that it does not cause loss in sensation at the application

site, possess a minimal risk for systemic toxicities or drug-drug interactions, are generally well-tolerated, and that the adverse reactions if any like dermatitis, erythema, a burning sensation, bruising, petechia, pruritus, vesicle formation, and blistering or exfoliation of the skin resolve quickly [29, 30]. From a mechanistic view point low concentrations lidocaine mediates its anesthetic effect by inhibiting generation and propagation of nerve impulses of the sensory neurons [31, 32]. All these factors are very beneficial and make lidocaine suitable for focal neuropathic pain, with or without allodynia [1, 33]. Finally from a cost factor perspective, 10% lidocaine cost around 250 Indian rupees (66 INR = 1 \$) and one bottle can be useful for at least 75 patients. In lieu of all these observations it can be deduced that the commonly used 10% lidocaine spray used for procedures like laryngoscopy, bronchoscopy, tonsillectomy and endotracheal intubation is very beneficial, easy to use, safe and inexpensive for use as an analgesic to mitigate injection pain especially in the resource deficient developing countries. Future studies are planned to assess its use in pediatric conditions.

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