Lidocaine/Tetracaine Patch For Treatment of Topical Anesthesia Before Vascular Access

Health Technology Appraisal

Issued:October 2014

- **بيانات المستحضر محل الدراسة:**

Intervention	Lidocaine/Tetracaine Patch
Company name	Kahira Pharmaceutical & chemical Industries Company For Bioxell Pharma
Comparator	Lidocaine/Prilocaine Cream

- **الهدف:**

تقييم الفعالية لقاء التكلفة لمستحضر Lidocaine/Tetracaine Cream فى حالات التخدير الموضعى وذلك لضمان أفضل النتائج العلاجية بالنسبة للمريض وبأقل تكلفة ممكنة من خلال الإلتزام بالخطوط العلاجية الاسترشادية العالمية وفي ضوء الممارسة الإكلينيكية المحلية.

- **توصية لجنة اقتصاديات الدواء:**

بناء علي الطلب المحول من إدراة التسعيرة لعمل دراسة اقتصادية للتأكد من وجود فائدة علاجية إضافية لمستحضر Lidocaine/Tetracaine Cream مقارنة بمستحضر Lidocaine/Prilocaine Cream وذلك بعد تظلم الشركة بمقارنة مستحضرها بمستحضر ال (Lidocaine/Prilocaine Cream) إذ ترى الشركة نظرا لوجود مادة ال Tetracaine والغير موجودة في مستحضر Lidocaine/Prilocaine Cream والذي تمت المقارنة به ونظرا لارتفاع تكلفتها فانها لا توافق على السعر المقترح من لجنة التسعيرة .

وعليه فقد تبين من الدراسة التي قامت بها وحدة اقتصاديات الدواء (scenario analysis) والتى قارنت (Lidocaine 70mg+Tetracaine 70mg) في صورة Novel heat-aided patch بمستحضر الذي يحتوي على (Lidocaine 25mg + Prilocaine 25mg)/ml وافادت بان مستحضر Lidocaine/Tetracaine Patch قام بتخدير فعال في خلال ١٠ دقائق مقارنة بال Lidocaine/Prilocaine Cream . وايضاً اثبتت الدراسة ان ال Pain intensity (rated by Visual Analouge Scale) يتساوى بين المستحضرين بعد ٦٠ دقيقة

ولذلك أوصت اللجنة بان يتم مقارنة المستحضر Lidocaine /Tetracaine Cream بمستحضر Lidocaine/Prilocaine Cream بدون اي ميزه سعرية حيث الميزة العلاجية الاضافية ترجع الي استخدام Heated-patch delivery system في حين ان المستحضر المقدم في صورة Cream.

- علما ان الدراسة التي قامت باجرائها وحدة اقتصاديات الدواء شملت بيانات التكلفة الخاصة بالمستحضرات التي تم تجميعها من إدارة التسعيرة. كما تم تجميع البيانات الخاصة بالقيمة العلاجية الناتجه عن جودة الحياه المعيشية للمريض ونسبة الحالات المستجيبة للعلاج من الدراسات المنشورة عالميًا .

Tel.: +202 – 23684288 +202 – 23648769 +202 -25354100 Ext.: 1902 Fax: +202 – 23684194
Email: peunit@eda.mohp.gov.eg Website: www.eda.mohp.gov.eg

English Summary:

Economic Evaluation Of Lidocaine/Tetracaine Patch Versus Lidocaine/Prilocaine Cream For Topical Anesthesia Before Vascular Access In Egypt

- **Introduction**

Many clinical procedures, including vine puncture, arterial puncture, lumbar puncture, percutaneous venous catheter placement, and dermatological procedures, may be associated with pain or discomfort. Consequently, the procedural pain, associated stress and anxiety involved for some patients represent a significant clinical concern, which is often addressed by the use of topical anesthesia. But, intact skin presents a significant barrier to available topical anesthetic preparations. This means that many topical anesthetic preparations must be applied at least 45–60 min before the clinical procedure to achieve the desired level of anesthesia.

In addition, current creams or gel-based preparations may require the use of occlusive dressings, adding to the time required for their application. These factors place an additional burden on clinical staff and can lead to delays in administering the planned procedure (1).

The lidocaine/tetracaine patch (lidocaine 70 mg/tetracaine 70 mg) is a novel drug delivery system designed to warm the skin and enhance the delivery of local anaesthetics through the skin.This study conducted to compare cost-effectiveness of the lidocaine/tetracaine patch versus lidocaine/prilocaine cream when applied within 1 hour of conducting vascular access procedures in adult volunteers.

- **Objective:**

The aim of this study was to estimate the cost-effectiveness of lidocaine/tetracaine patch versus lidocaine/prilocaine cream for topical anaesthesia before vascular access.

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- **Economic evaluation Key Features:[2]**

Key Features:	
Year of the document	October 2014
Affiliation of authors	Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs
Purpose of the document	To assess the cost-effectiveness of Lidocaine/Tetracaine with lidocaine/prilocaine cream for topical anaesthesia before vascular access based on Egyptian clinical practice.
Standard reporting format included	yes
Disclosure	Yes
Target audience of funding/ author's interests	Public payers
Perspective	Societal perspective
Indication	local anesthesia on the skin
Target population	Public recipients
Subgroup analysis	Not done in the study.
Choice of comparator	Lidocaine/Prilocaine Cream is the routinely used intervention for this indication in such patients
Time horizon	A decision-tree model
Assumptions required	Yes
Analytical technique	CUA
Costs to be included	Official sources of unit cost data for products (The Ministry of Health Hospitals)
Source of costs	Direct medical costs included
Modeling	A decision-tree model
Systematic review of evidences	Yes
Preference for effectiveness over efficacy	Yes
Outcome measure	The primary efficacy endpoint was subject report of pain intensity using a 100 mm visual analogue scale (VAS).
Method to derive utility	The direct use of EQ-5D
Equity issues stated	All lives, life years, or QALYs should be valued equally, regardless of age, gender, or socioeconomic status of individuals in the population.
Discounting costs	No discount rate was used.
Discounting outcomes	No discount rate was used.

Sensitivity analysis-parameters and range	Critical component(s) in the calculation is varied through a relevant range or from worst case to best case.
Sensitivity analysis-methods	Probabilistic Sensitivity Analysis
Presenting results	Lidocaine/Tetracaine (Heated Patch Delivery System) is cost effective option for topical anaesthesia before vascular access when compared with lidocaine/prilocaine Cream
Incremental analysis	Yes
Total costs vs effectiveness (cost/effectiveness ratio)	Yes
Portability of results (Generalizability)	The generalizability and extent to which the clinical efficacy data and the economic data are representative is identified and discussed

- **Committee Discussion**

Decision analysis is a quantitative method for synthesizing data from numerous sources for the evaluation of treatment alternatives and was developed to determine the cost-effectiveness of lidocaine/tetracaine patch as important novel treatment for topical local anaesthesia. The present study demonstrate that use of lidocaine/tetracaine patch as a novel treatment option versus lidocaine/prilocaine cream for topical local anaesthesia, resulted in an incremental cost-effectiveness ratio (ICER) EGP 376.95 /quality-adjusted life year gained.

A key strength in this study that should be mentioned was the median visual analogue scale (VAS) scores that were obtained from a randomized, double-blind, paired study compared the effectiveness of the lidocaine/tetracaine patch with that of lidocaine/prilocaine cream for topical anesthesia before vascular access in 82 adult volunteers [1]. The results of this study are consistent with those of other studies of the lidocaine/tetracaine patch. The lidocaine/tetracaine patch has been shown to provide effective dermal anaesthesia vs placebo in adults and children [3,4,5 & 6]. Results from PSA indicate that Lidocaine/Tetracaine had a 100% chance of being cost-effective at our EGP 70,000 per QALY threshold.

One of the limitations that could have affected the outcome of the clinical trial is including control of room temperature and control of the amount of lidocaine/prilocaine cream applied under the plastic template. Although use of the plastic template that covered the same area as the lidocaine/tetracaine patch limited the amount of lidocaine/prilocaine cream applied to a certain extent, it is possible that the cream could have been more or less thinly applied each time.

Conclusion

The present study concludes that Lidocaine/Tetracaine (Heated Patch Delivery System) is cost effective option for topical anaesthesia before vascular access when compared with lidocaine/prilocaine (Cream) based on the threshold stated by world health organization (3xGDP/capita) for low and middle-income countries.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this article.

- **Appraisal Committee members**

Each technology appraisal is appraised by the PE Committee, which is one of CAPA's standing advisory committees and consist of members who represent different specialties such as statistics, clinical evidence, economics, medicine, clinical pharmacy and pharmacoeconomics. A list of the Committee members who took part in the discussions for this appraisal appears below:

Dr. Mahmoud El-Mahdawy, General Director of Hospital pharmacy administration, Central Administration for Pharmaceutical Affairs, Ministry of Health.

Dr. Gihan Hamdy, Head of Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs, Ministry of Health.

Dr. Abd Allah Mohammed, Expert at National Authority for the control of Biopharmaceuticals.

- **PEU project team**

- **Gihan Hamdy El-sisi**, Head of Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs, Ministry of Health.

- **Hossam Mohamed Abdallah,** Team member of Pharmacoeconomic Unit, Central Administration for Pharmaceutical Affairs, Ministry of Health.

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