PARTING LASER PERFORATOR

HEALTH TECHNOLOGY ASSESSMENT SECTION
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA

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Please contact: htamalaysia@moh.gov.my, if you would like further information.

Health Technology Assessment Section (MaHTAS),
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590 Putrajaya

Tel: 603 88831246

Fax: 603 8883 1230

Available at the following website: http://www.moh.gov.my

Prepared by:
Dr Junainah Sabirin
Principal Assistant Director
Health Technology Assessment Section (MaHTAS)
Ministry of Health Malaysia

Reviewed by:
Datin Dr Rugayah Bakri
Deputy Director
Health Technology Assessment Section (MaHTAS)
Ministry of Health Malaysia

External Reviewer
Dato' Dr Chang Kian Meng
Senior Consultant Haematologist
Ampang Hospital

DISCLOSURE

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EXECUTIVE SUMMARY

Introduction

Laser skin perforators work like lancets to perforate the skin to draw capillary blood. These devices produce a single pulse of laser light, which make a small hole in the fingertip. There are many brands of laser skin perforators. [redacted] is based on the erbium technology. It is a portable battery operated laser device. The device produces a single pulsed of laser light with a wavelength of 2.94µm which ablates the skin for collecting capillary blood samples. This technology review was conducted following a request from the Office of Minister of Health, following a proposal by a company to sell [redacted] Parting Laser Perforator, [redacted] which is made in [redacted] to Ministry of Health Hospitals.

Objective /aim

To assess the safety, effectiveness and cost-effectiveness of Parting Laser Perforator.

Results and conclusions

There was limited evidence to show that [redacted] Parting Laser Perforator, [redacted] and other brands of laser skin perforators are safe. There was limited evidence to show that there was insignificant difference between laser skin perforators and stainless steel lancet with regards to pain, convenience and methods of preference.

There was no retrievable evidence on the effectiveness of [redacted] Parting Laser Perforator, [redacted] for collection of capillary blood sample. However, with regards to other laser skin perforators there was limited evidence to show that they are as effective as stainless steel lancet for obtaining capillary blood in patients with diabetes. From the retrievable evidence, the results showed no significant difference between capillary blood obtained for glucose and haematocrit test using the two methods. However, the estimation of potassium level in the capillary blood obtained using laser skin perforator was not reliable.

There was no retrievable evidence on the cost-effectiveness of [redacted] Parting Laser Perforator, [redacted] or other brands of laser skin perforators.

Recommendation

Based on the above review, more clinical research is warranted for this technology. Laser skin perforators do not seem to be superior compared to the conventional lancet in obtaining capillary blood, hence, it cannot be recommended for routine use.

Methods

Electronic databases which included PubMed, Medline from 1950 to week 4 2009, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Review-Cochrane database of systematic reviews, HTA Databases, Horizon Scanning database (Euro scan, Australia and New Zealand Horizon Scanning), FDA website, MHRA, and Google were searched for published reports. Relevant articles were critically appraised and evidence graded using US / Canadian Preventive Services Task Force.

PARTING LASER PERFORATOR

1. INTRODUCTION

Capillaries are tiny blood vessels near the surface of the skin. **C**apillary blood sample is a blood sample collected by pricking the skin. Capillary blood sample is usually obtained from a finger prick or heel puncture. However, capillary blood sample can also be obtained from the ear lobe. It can be used to monitor blood glucose levels, drug levels, blood gases, full blood counts, urea and electrolytes and newborn bloodspot screening tests.[1]

Capillary blood sample can be obtained through many methods such as conventional methods using lancets and other lancing devices or newer methods such as laser skin perforators. Lancets and other lancing devices are sharp blades or needles used to obtain blood samples from capillaries. There are many types of lancets; some have protective caps or other special features. Most automatic lancing devices consist of a hand-held tube with a spring-loaded lancet and come with different lancet covers to allow different amounts of skin penetration.[2]

Laser skin perforators work like lancets to perforate the skin to draw capillary blood. These devices produce a single pulse of laser light, which make a small hole in the fingertip.[2] There are many brands of laser skin perforators such as Lasette P-200 skin perforator, MCL 29 Dermablate erbium:yttrium-aluminum-garnet (ER:YAG) Laser System, ERMED-304 laser perforator, Laser perforater SIGMA and Biomed TZD-CX Series Laser Perforator.[3,4,5,6,7] Lasette P-200 laser perforator by Cell Robotics was the first portable laser perforator and was cleared for marketing by United States of America Food and Drug Administration (FDA) in December 1998. It is classified under Class II medical device and is indicated for use by qualified healthcare professionals for screening purposes and should not be used to collect samples for use in analyzers that require complex sample transfer procedures.[3]

This technology review was conducted following a request from the Office of Minister of Health, following a proposal by a company to sell [redacted] Parting Laser Perforator, [redacted] which is made in [redacted] to Ministry of Health Hospitals.

2. OBJECTIVE /AIM

The objective of this systematic review was to assess the safety, effectiveness and cost-effectiveness of Parting Laser Perforator.

3. TECHNICAL FEATURES

[redacted] Parting Laser Perforator, [redacted]

[redacted] Parting Laser Perforator, [redacted] is based on the erbium technology which was researched and developed by a nuclear physics research institute in Russia. It is produced by [redacted].[7] It is a portable battery operated laser device. The device produces a single pulsed of laser light with a wavelength of 2.94µm which ablates the skin and allows the collection of capillary blood samples.[7]

It is claimed to be painless, no cross contamination, high-purity of blood sample, easier collection process and rapid micro-wound healing. It can be used to collect capillary blood from fingers, from the heel as well as from the earlobe.

It has several features such as parting structure, airproofed disposable laser shield, visual angle adjustable LCD, single hand operation and no memory effect of Polymer Lithium Ion Battery.

4. Methodology

4.1. Searching

Electronic databases were searched, which included PubMed, Medline from 1950 to week 4 2009, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Review-Cochrane database of systematic reviews, HTA Databases, Horizon Scanning database (Euro scan, Australia and New Zealand Horizon Scanning), FDA website, MHRA, and Google for published reports. There was no limitation in the search. Additional articles were identified from reviewing the bibliographies of retrieved articles

and from the documents submitted by the company. Personal communication was also carried out by telephone calls.

The search strategy used the terms, which are either used singly or in various combinations: "Parting Laser Perforator", "Laser perforator", lancet, RCT, "laser skin perforator", "[redacted] laser perforator".

4.2. Selection

All published articles related to safety, effectiveness and cost-effectiveness of laser skin perforators were included. Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and evidence was graded according to US/Canadian Preventive Services Task Force (Appendix 1)

5. RESULTS AND DISCUSSION

The search strategies yielded one article on the CE Certificate issued to TZD-CX-series laser perforator by TUVSUD, two articles on US FDA premarket nortification for Lassette P-200 laser skin perforator and MCL 29 Dermablate ER:YAG Laser System.

There was no retrievable evidence on the effectiveness of Parting Laser Perforator, [redacted] for collection of capillary blood sample. However, there were two articles related to the safety and effectiveness of other brands of laser perforators for collection of capillary blood sample (one letter to the editor and one Randomized Controlled Trial) were retrieved.

5.1. SAFETY

TZD-CX-series laser perforator received European Union CE certificate by TUVSUD which looked into the safety and performance of the device in 2007.[7,9] There was no retrievable evidence on approval by US FDA and on the adverse events related to its use.

On the other hand, other type of laser skin perforators such as Lassette P-200 and MCL 29 Dermablate ER:YAG Laser System received 510(K) premarket nortification from US FDA.[3,4]

5.2. EFFECTIVENESS

There was no retrievable evidence to show effectiveness of [redacted] laser perforator. However, Burge *et al.*, in his letter to the editor, describes two studies using the same protocol that looked into the safety and effectiveness of using laser skin perforators for determination of capillary blood glucose (CBG) and haematocrit compared with standard stainless steel. Studies were conducted in the University of New Mexico Health Sciences Centre (study 1) and Lovelace Medical Centre (study 2).[10]

Both studies involved capillary blood sampling from the fingertips of 100 patients with type 1 or type 2diabetes. Blood was sampled from randomly selected finger of the non dominant hand using laser skin perforator (Lasette) and from the adjacent finger using a standard stainless steel lancet (Ultrafine Lancet). The order of sampling was also randomized. Blood was applied first to the CBG strip and then collected into the capillary tubes for haematocrit determination. The amount of blood sampled was 200 micro litre in study 1 and 100 micro litre in study 2.
A survey that assessed the attitudes about both sampling methods was also conducted and all the subjects were followed up after 48 hours to confirm wound healing.[10]

Of the 95 subjects included in study 1, data were lacking from 21 subjects (in 18 subjects, there was failure to obtain sufficient sample with the Lasette and in 3 subjects there was failure of the battery charger on the Lasette). There was no statistically significant difference in the results of CBG using the two methods (CBG using Lasette was 11.05±5.94 mmol/l and CBG using stainless steel lancet was 10.94±5.66 mmol/l, p =0.30). The results were highly correlated (correlation coefficient = 0.97). Similar findings were also reported for the haematocrit. Haematocrit using Lasette was 45± 5% and haematocrit using stainless steel lancet was 45± 8%, p=0.75. The results were highly correlated (correlation coefficient = 0.90).[10]

Of the 99 subjects included in study 2, data was lacking from 1 subject due to failure to obtain sufficient sample with the Lasette. There was no statistically significant difference in the results of CBG using the two methods (CBG using Lasette was 8.27±3.77 mmol/l and CBG using stainless steel lancet was 8.27±3.72 mmol/l, p =0.32). The results were highly correlated (correlation coefficient = 0.98). Similar findings were also reported for the haematocrit. Haematocrit using Lasette was 45± 5% and haematocrit using stainless steel lancet was 45±4%, p=0.86. The results were highly correlated (correlation coefficient = 0.86). [10]

There was no significant difference between the two methods with regards to pain, convenience and methods of preference. However, the study subjects perceived greater difficulty in obtaining blood sample with Lasette compared with the standard stainless steel lancet in study 1, ($p < 0.001$). In study 1, all patients reported satisfactory wound healing at 48 hour from telephone calls follow-up. In study 2, 97% of patients reported satisfactory wound healing with Lasette. [10]

The authors concluded that the Lassette laser skin perforator, compared to stainless steel lancets, is safe and effective for obtaining capillary blood samples in patients with diabetes. These two methods for sampling capillary blood resulted in equivalent determination of CBG and haematocrit. The optimal clinical indication for using Lasette remains to be determined. [10]

Fonseca *et al.,* conducted a study to determine the safety and efficacy of portable pulsed Er:YAG laser in obtaining blood sample from patients and to determine whether the laser radiant energy alters the level of various components of the blood. He compared the laboratory values of blood samples obtained using the laser with the conventional lancet.

He also evaluated patient and user preferences using questionnaire. His study involved 100 diabetic patients attending diabetic clinic who were randomized to have their capillary blood sampling from their fingertips performed either by the laser or a conventional lancet first and subsequently with the other device. The study showed that in 97% of the time, adequate blood was obtained with both devices. He noted that the potassium level in the blood obtained with the laser was significantly elevated and unsuitable for clinical decision making in many cases. There was no difference in the plasma or blood concentrations of any of the parameter tested (haematocrit, blood urea nitrogen, sodium, chloride, bicarbonate, haemoglobin, HbA1c, and blood glucose) when either laser or the lancet was used. He also noted that although patients felt greater pain and experienced slower healing with laser ($p<0.01$) but these problems were not serious. There was no significant difference in patient preference. The authors concluded that the laser device has potential to obtain a blood sample for routine tests without a needle but further work is needed to alter the laser energy so that haemolysis can be decreased, thus enabling a more reliable potassium estimation.[11] level I.

5.3. COST- EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of [redacted] Parting Laser Perforator, [redacted] or the other brands of laser skin perforators for collection of capillary blood sample.

The price quoted by the company for a unit of [redacted] Parting Laser Perforator, [redacted] was [redacted]

6. CONCLUSION

6.1. SAFETY

There was limited evidence to show that [redacted] Parting Laser Perforator, [redacted] and other brands of laser skin perforators are safe.

There was limited evidence to show that there was insignificant difference between laser skin perforators and stainless steel lancet with regards to pain, convenience and methods of preference.

6.2. EFFECTIVENESS

There was no retrievable evidence on the effectiveness of [redacted] Parting Laser Perforator, [redacted] for collection of capillary blood sample. However, with regards to other laser skin perforators there was limited evidence to show that they are as effective as stainless steel lancet for obtaining capillary blood in patients with diabetes.

From the retrievable evidence, the results showed no significant difference between capillary blood obtained for glucose and haematocrit test using the two methods. However, the estimation of potassium level in the capillary blood obtained using laser skin perforator was not reliable.

6.3. COST- EFFECTIVENESS

There was no retrievable evidence on the cost-effectiveness of [redacted] Parting Laser Perforator, [redacted] or other brands of laser skin perforators.

7. RECOMMENDATION

Based on the above review, more clinical research is warranted for this technology. Laser skin perforators do not seem to be superior compared to the conventional lancet in obtaining capillary blood, hence, it cannot be recommended for routine use.

8. REFERENCES

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9. APPENDIX

9.1 Appendix 1

DESIGNATION OF LEVELS OF EVIDENCE

I Evidence obtained from at least one properly designed randomized controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)