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## Comparative Evaluation Of The Efficacy Of Computer Controlled Local Anaesthesia Delivery System (CCLAD) In Reducing Pain During Injection Of Local Anaesthesia Vs Traditional Method Of Local Anaesthesia Injections: A Systematic Review.

Sagar Joshi, Kalyani Bhate\*, Kunal Gajendragadkar, Vivek Pawar, Sushmita Mitra, and Santhosh Kumar SN.

Dr.D.Y. Patil Vidyapeeth, DYPDCH, Department of Oral and Maxillofacial Surgery, Pune, Maharashtra, INDIA.

### ABSTRACT

To compare the efficacy of Computer Controlled Local Anaesthesia Delivery System(CCLAD) in reducing pain during injection of Local anaesthesia vs traditional method of Local anaesthesia injection. Electronic search of PubMed, Google Scholar, Institutional Library, EMBASE, Ind Med and E-mail to authors revealing information about CCLAD. CCLAD was used to inject local anaesthesia on one side while conventional syringe on other side. 36 studies and one additional record from other information sources were identified through search of data bases. After 7 studies were removed for being duplicate and 16 were excluded for not meeting eligibility criteria, 14 studies remained . Out of these 2 studies were excluded as one was non human study and other was not available in full text form. Thus total 6 studies were included in qualitative synthesis and total estimate of was 7. The studies revealed that CCLAD was equally effective to conventional syringe, also causing lesser pain during injection and better patient comfort levels. CCLAD is more effective than conventional syringe for delivering anaesthesia for pain control during local anaesthesia. It has good scope in developing countries.

**Keywords:** CCLAD, WAND, Conventional injection, Pain, Visual analogue scale.

*\*Corresponding author*

## INTRODUCTION

Use of local anaesthetic injections is one of the most anxiety provoking procedures. [1] Though it produces pain and anxiety, its proper administration provides relatively painless treatment and also helps in gaining patient's cooperation. According to the American Dental Association, fear of pain is the most important factor preventing patients from visiting their dentists. Different kinds of fears related to previous clinical experience affect patient's attitudes towards local anaesthesia and dentist. [2]

The conventional local anaesthesia administration has few disadvantages like pain on prick, pressure while administration, irregular pressure and uneven flow. The two aspects of local anaesthetic injections are needle insertion and deposition of solution. [3] It has been observed that a painless or less painful needle insertion can reduce some of the fear and anxiety of the patient. In palatal injections, the pressure of injection increases patient's discomfort. [4] Dental injection pain can also occur due to too rapid administration of local anaesthetic into the soft tissue. This rapid injection leads to tearing of mucosa followed by immediate pain and delayed soreness. This disadvantage of conventional injection technique needs to be addressed by alternative method. [5]

The field of local anaesthesia has witnessed many developments in the last century and numbers of different techniques have evolved. Various newer techniques such as Dental Vibe, Vibraject and CCLAD etc have evolved for painless administration of local anaesthetic injections and further research is going on.

These studies show that significant reduction in pain during local anaesthetic injection can be achieved with these devices. However, no single technique/ device offers totally painless procedure till date.

The WAND (Milestone Scientific, Livingston NJ) is a computer controlled local anaesthesia delivery system it drives local anaesthetic from a conventional local anaesthetic cartridge through plastic microtubing into a plastic handle to which a luer-lok needle is attached. The computer controlled flow is initiated by exerting pressure on a foot pedal. The pump allows administration of local anaesthetic at slow but constant rate and the computer compensates for variation in resistance to flow. A continuous positive pressure creates an anaesthetic pathway prior to needle insertion. The combination of an anaesthetic pathway and controlled flow rate results in a virtually imperceptible injection and rapid onset of profound anaesthesia. [6]

Thus, different studies are being carried out regarding the efficacy of CCLAD, but not a single systematic review has been published. Hence, the purpose of our study is to compare the efficacy of Computer controlled anaesthesia delivery system (CCLAD) in reducing pain during injection of Local anaesthesia vs traditional method of local anaesthesia injection

## FOCUSED QUESTION

How useful is CCLAD in reducing pain during injection of Local anaesthesia for patients undergoing dental treatment?

## MATERIALS AND METHODS

The objective of this study was to compare the response to pain during injection of local anaesthesia delivered through CCLAD and traditional injection methods.

### Selection Criteria

Studies in English or those having detailed summary in English, studies that provided information regarding use of CCLAD for local anaesthesia, studies published between first January 1995 till first December 2016 as well as randomised controlled trials with requisite data on CCLAD were included in this study. Case reports, abstracts, letters to editors, editorials and in-vitro studies were excluded from this study. Studies that did not use any objective methods to assess pain during injection of local anaesthesia were also excluded from this study.

### Information sources

Keeping in mind the purpose of this study, a systematic review was designed according to PRISMA (Preferred Reporting items for Systematic reviews and Meta analysis) 2009 check list. A comprehensive search of the literature was undertaken. A date restriction from 1995 till date and language restriction of English was put while undertaking electronic search. The electronic search included PubMed, Google Scholar, Ind Med, EMBASE and institutional library. In addition, the bibliographies of included studies and studies were hand searched to identify potentially eligible studies not captured by electronic search. E-mail communication to authors of potentially eligible studies was also done to obtain the same. In addition a manual search of oral and maxillofacial related journals was performed, including International Journal of Oral and Maxillofacial Surgery, British Journal of Oral and Maxillofacial Surgery, Journal of Oral and Maxillofacial Surgery, Oral Surgery Oral Medicine Oral Pathology Oral Radiology and Endodontology, Journal of Cranio-Maxillo-Facial Surgery, Journal of Craniofacial Surgery, Journal of Maxillofacial and Oral Surgery. The reference list of identified studies on the subject was also scanned for possible additional studies.

Search terms used were CCLAD/AMSA/WAND/STA, Conventional injection/needle/block and Pain/visual analogue scale/ hyperalgesia. We used one or more combination of the following search strategy: CCLAD and Conventional Local anaesthesia injection, CCLAD and Pain response, WAND and conventional local anaesthesia, AMSA and conventional local anaesthesia, STA and conventional local anaesthesia injection and Conventional local anaesthesia injection and pain response.

**Study selection:** Preliminary screening consisted 36 studies identified through search of data bases and one additional record from other information sources. After 7 studies were removed for being duplicate and 16 were excluded for not meeting eligibility criteria, 14 studies remained. Out of these 2 studies were excluded as one was non human study and other was not available in full text form. Thus total 6 studies were included in qualitative synthesis and total estimate of was 7. The studies revealed that CCLAD was equally effective to conventional syringe, also causing lesser pain during injection and better patient comfort levels.

These were independently screened by three reviewers (SJ, SM and VP). At first, the studies were screened by title and abstract. As a second step, full text studies were obtained when they fulfilled the criteria of the study. Any disagreement between any two reviewers was resolved after additional discussions. All the selected data was individually checked by the other reviewers (KB and KG). After this a data extraction sheet was prepared.

#### **Data collection process**

A standard pilot form in excel sheet, for data extraction, was initially used and then all those headings not applicable for review were removed. Data extraction was done for one article and this form was reviewed by an expert and finalised. From the studies included in the final analysis, the following data were extracted:

1. Study Id
2. Location- The country in which study took place
3. Author- Name of author
4. Year of publication- The year in which the study was published
5. Study design- If the study was a control or a clinical trial,blinding.
6. Sample size- Number of participants included in the study.
7. Settings- Dental speciality in which study was conducted
8. Product-CCLAD
9. Intervention- Injection technique used for CCLAD.
10. Comparison- Conventional syringe
11. Technique- Injection technique used for conventional syringe
12. Outcome- Result of the study
13. Conclusion.- Comments of the authors (SJ,VP,KB)

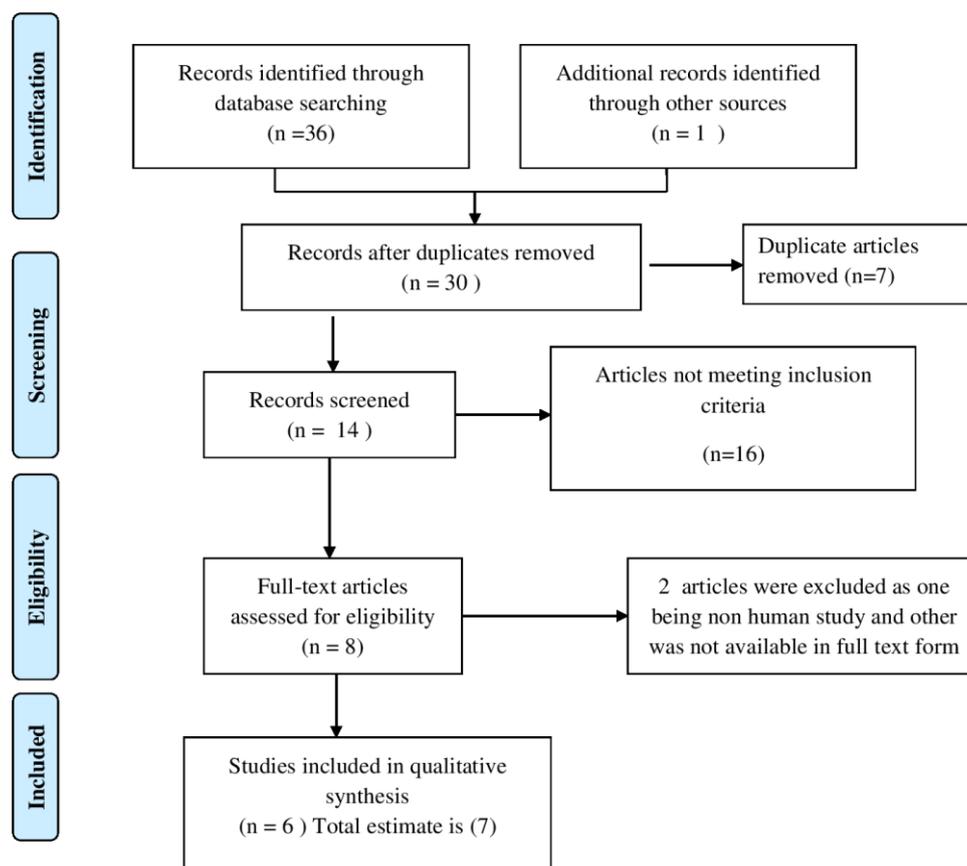
#### **SUMMARY OF EVIDENCE**

The CCLAD system Wand™ was developed in 1997 (Milestone Scientific, Inc.,Livingston,N.J). [7,8] It is available in two types i.e. Comfort Control Syringe (CCs) and Single tooth anesthesia (STA).

The CCLAD system is effective because it controls pressure during injection and thus reduces pain during injection. As it consists of light weight hand piece with needle and is held in a pen grasp, it causes less pressure on clinician's thumb joint. [6]

Murat Yenisey in the year 2009 conducted a study, using WAND Computer controlled local anaesthesia. He compared the pain levels on opposite sides of the maxilla at needle insertion during delivery of local anaesthetic solution and tooth preparation for both conventional and anterior middle superior alveolar (AMSA) technique with the WAND computer controlled local anaesthesia application. He found that the WAND technique had a lower pain level compared to conventional injection for needle insertion. In the anaesthetic delivery phase, pain level for the WAND technique was lower. [2]

Shelly Lee et al in the year 2004 conducted a study on 40 patients. The purpose of their study was to determine the anaesthetic efficacy of anterior middle superior alveolar (AMSA) injection using the computer assisted WAND PLUS injection system versus a conventional syringe. They found that AMSA injection using the computer assisted injection system was more successful than conventional syringe technique. [9]



Jerry W Nicholson et al did a study in the year 2000 on 30 patients in crossover half mouth design. Each patient received one injection with the syringe and one injection with WAND at each appointment. At the second visit, injections were performed on opposite side of mouth. Injection device and location were reversed from the first session so that each patient ultimately received maxillary infiltration and mandibular block injections with both the syringe and the WAND. They concluded that mean injection discomfort ratings with WAND were lower than with syringe but not significantly. Postoperative discomfort for mandibular block injections was significantly less using the WAND system than with the syringe. [10]

Peter M Loomer and Dorothy A. Perry conducted a study in the year 2004 on 20 healthy adult patients. The aim of this study is to compare administration of local anaesthetic using a computer- controlled delivery device with an aspirating syringe for the therapeutic scaling and root planing. The Anterior Middle Superior Alveolar (AMSA) injection was compared with greater palatine (GP), Nasopalatine (NP), anterior

superior alveolar (ASA) and middle superior alveolar (MSA) injections. They conclude that injections administered using computer controlled device was scored regularly as less painful than were injections administered using the conventional syringe. [11]

E G Grace et al conducted a survey questionnaire study in 2002 over 260 patients. Aim of this study was computer controlled dental anaesthetic delivery system studied with the objective of evaluating and comparing the unit to the traditional method of anaesthetic delivery. They conclude that computer controlled dental anaesthetic injections and traditional anaesthetic injections were accepted equally well by both dentists and patients. [12]

Yogesh kumar et al conducted a study in 2015 on 120 children. Type of study is randomized controlled trial (RCT) study. Aim of this study is to compare pain perception, behavioural response and the associated physiological parameters while receiving local anaesthesia injection with cartridge syringe and computer controlled local anaesthetic delivery system (CCLAD) over two consecutive visits. They conclude that, injection with CCLAD causes lesser pain response, disruptive behaviour and pulse rate. The CCLAD injections were comparable to conventional injections using benzocaine topical applicator and significantly better than no topical gel application in regards to pain perception and behavioural response of children. [1]

With the purpose of comparing the efficacy of CCLAD in reducing pain during local anaesthesia injection, six studies were identified. These fit the inclusion criteria. Out of these six studies, seven settings of comparison between CCLAD and conventional syringe technique were established.

Out of seven settings three studies, i.e. two by Yogesh Kumar et al and one by Murat Yenisey were conducted in India and Turkey, respectively. [1, 2] Rest all the studies were conducted at various locations in USA, viz. Ohio, Texas, California and Baltimore. This seems to imply more use of CCLAD in USA than other countries.

The year of publication of these studies ranges from 2001 to 2015. The studies from USA were conducted from 2000 to 2004. [6, 9, 10, 12] The study in Turkey was in 2009 while, the Indian studies were in 2015. From this data it appears after its introduction in 1997, its use was restricted to USA while now it is gaining popularity in developing country like India.

The studies included in this systematic review showed a great variation in their study design. Two studies by Yogesh Kumar et al were randomized controlled trials. [1] The study conducted by E.G. Grace was a questionnaire based study. [12] The rest of the studies were case controlled studies in which two studies by Shelly Lee et al and Peter M. Loomer and Dorothy A. Perry were single blind studies. [9, 11] The crossover design was used by Jerry W. Nicolson et al and Peter M. Loomer and Dorothy A. Perry [10, 11]. The comparative split mouth study design was used by Murat Yenisey and Shelly Lee et al. [2, 9]

Murat Yenisey used a sample size of sixteen patients, Shelly Lee et al used a sample size of forty patients, Jerry W Nicolson used a sample size of thirty patients, Peter M Loomer and Dorothy A Perry used a sample size of twenty patients. [2, 9, 10, 11] The sample size of study conducted by Yogesh Kumar et al and E.G. Grace were 120 and 260 patients. [1, 12] The sample size of study conducted by Murat Yenisey and Peter M Loomer and Dorothy A. Perry were too small for deriving reliable conclusions. [2, 11]

Out of the seven settings of selected studies considerable variety was evident. Two studies by Yogesh Kumar et al were conducted in Pedodontia, while rest were one each in Prosthodontia, Endodontics, general dentistry and two studies held in Periodontics. [1, 2, 9-12] The wide range of clinical settings in all these studies hereby proves use of CCLAD in all types of procedures in dentistry.

E.G. Grace in his study used the Computer Controlled System by Dentsply, while the rest of the studies used WAND and WAND plus (Shelly Lee et al) by Milestone scientific, Livingston NJ. [12, 9] This seems to indicate that the WAND system is more popular than the CCS.

The CCLAD was given with anterior middle superior alveolar (AMSA) technique in three studies. [2,9,11] Four other studies used different anaesthesia techniques. The AMSA technique has gained popularity with the advent CCLAD.

The CCLAD system was compared with the conventional syringe in all the studies. The studies using AMSA technique compared it with buccal infiltration, AMSA or other maxillary infiltration techniques. The study conducted by Yogesh Kumar et al was the only study where topical anaesthesia with the help of anaesthetic gel was applied before using conventional syringes for local anaesthesia injections. [1]

Conventional syringe technique was considered less effective than CCLAD in maxillary as well as mandibular local anaesthesia injections. The patient comfort was also better with CCLAD. In Pedodontia setting, the children showed less disruptive behaviour with CCLAD than conventional syringe. The pulpal anaesthesia, in Endodontics, was achieved for sixty minutes with no collateral anaesthesia to the lips and facial muscles. The pain scores for maxillary palatal injections was much lower for AMSA with CCLAD than conventional syringe anaesthesia injections with anterior superior alveolar (ASA), middle superior alveolar (MSA), greater palatine (GP) and nasopalatine (NP). This may be attributed to slow and consistent speed of deposition of anaesthetic solution with CCLAD. This allows for comfortable penetration in to the fibrous palatal tissue and adequate diffusion through the tissues in the centre of hard palate to the bone and nerve tissue. Only the study conducted by Yogesh Kumar et al wherein he conducted RCT of comparison of CCLAD to conventional syringe with topical gel application, no advantage of CCLAD over conventional syringe was noted. [1] This may be due to anaesthetic effect of topical gel to reduce pain of prick of conventional syringe and discomfort and pressure sensation during injections.

The CCLAD thus is more successful than conventional syringe in six out of seven estimate studies. The CCLAD with AMSA technique is recommended by three out of seven studies. [2, 9, 11]

#### LIMITATIONS

6 studies were comparative evaluation and one was questionnaire based study. A degree of bias to new injection technique may have hampered the patients' perception to evaluate.

#### REMARKS

This systematic review pointed towards use of CCLAD in all dental specialities but none of the studies has made any mention about the cost of the CCLAD machine. In developing countries like India, economic factors dictate choice of therapy used furthermore CCLAD system needs training prior to its use. Though not difficult the conventional needle syringe technique is much easier to learn by paramedical staff than CCLAD. The recurring expenditure of CCLAD is much more than conventional needle. It is easier to manage multiple patients in any outpatient department (OPD) with conventional method and it is difficult to have a multiple CCLAD systems in the OPD.

Thus, though our systematic review concludes advantage of CCLAD in dentistry, the above mentioned limitations may hamper its use in day to day practice. Unfortunately, because of clinical heterogeneity amongst the studies, a synthetic meta-analysis could not be performed. Therefore, it is difficult to draw a conclusion that CCLAD is better than conventional method, even though individual studies claim it to be so.

#### CONCLUSION

This systematic review was conducted to evaluate how useful CCLAD is in reducing pain during injection of local anaesthesia. This was done by comparing the efficacy of CCLAD in reducing pain of injection during the injection of local anaesthesia and conventional anaesthesia of local anaesthesia injections. A comprehensive electronic search of literature was undertaken. Out of which six studies that fits the inclusion criteria settings were selected. Six studies have seven different settings. Out of seven settings six studies shows that local anaesthesia injection with CCLAD is less painful than conventional anaesthesia injections. One study shows that injection with CCLAD and injection with topical anaesthetic gel were comparable. If oral surgeons are trained to use CCLAD equipment the pain and discomfort experienced by patient will drastically reduce and patient will overcome the fear of anxiety.

### FUTURE IMPLICATIONS

Though CCLAD is not popular yet in developing countries like India, keeping in mind the advantages it has over the traditional injection technique promising results could be expected in the near future but a study can be done on cost effectiveness of CCLAD also a multicentric randomized controlled trial with larger sample size will help to confirm results of this review.

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