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Comparative evaluation of machine assisted irrigation activation technique and conventional syringe irrigation on postoperative pain in patients undergoing endodontic treatment: A Systematic review and meta-analysis

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Abstract--Objective: This systematic review and meta-analysis aimed to assess whether machine- assisted agitation resulted in less postoperative pain (PP) compared with syringe irrigation with needle alone in adult patients undergoing root canal treatment. Methodology: PICO strategy was used to electronically search key terms in the PubMed, Science Direct, Cochrane Library, Google Scholar and Wiley Online databases up to 2021 for randomized control trials (RCTs) with an observation period of at least 6 hours. The bias risk for RCTs was assessed using the Cochrane risk of bias tool. Meta-analysis was performed using RevMan 5.4 (RevMan 5.4,

The Nordic Cochrane Centre, Copenhagen). Results: A total of 9 studies (for systematic review) including 1075 patients with a 565/530 male to female ratio and a mean age of 40.5 years met the inclusion criteria. Out of 9, 6 studies were selected for the meta-analysis. Meta-analysis of the 6 studies indicated that overall, the use of machine-assisted irrigation technique showed better postoperative pain reduction than conventional syringe irrigation. Conclusion: Overall, machine-assisted irrigation causes reduction in postoperative pain compared to conventional syringe irrigation.

Keywords---Machine-assisted irrigation, conventional syringe irrigation, endodontic, postoperative pain, meta-analysis.

Introduction

Pain is defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or a sensation described in terms of such damage (1). According to a recent systematic review, the prevalence of postoperative pain (PP) following endodontic treatment during the first 24 hours is 40%, which is further reduced to 11% after 7 days (2). Besides general factors like age, gender and psychology, the pain may be associated with various factors, such as microbial, inflammatory, and/or immune-related factors. (3,4) One such factor is various irrigants and irrigation techniques. Various methods have been developed in order to provide effective delivery of the irrigating agents to disinfect the root canal system thoroughly. (5) These systems might be divided into two broad categories, manual agitation techniques and machine-assisted agitation devices. (6)

The traditional method of syringe irrigation has been shown to be incapable of reaching relatively inaccessible areas such as the apical and isthmus regions. Its stream action is relatively weak and depends on both root canal anatomy and the depth of the needle penetration. Thus, different irrigation agitation techniques have been proposed to improve the efficacy of irrigation solutions within the root canal system (7).

Machine-aided irrigation exerts various effects like mechanical effects through the delivery of streaming forces to the root canal walls, chemical effects through the exertion of specific effects of active components on the organic and inorganic remains and biological effects through inactivation of the microorganisms inside the canal. Machine-assisted irrigation techniques include sonic and ultrasonic as well as newer systems like apical negative pressure irrigation. (8)

Previously published systematic reviews have assessed the cleaning, disinfection, and/or decontaminating capacity of different irrigation agitation methods. None of these reviews were

conducted with the aim of relating these with post-operative pain. Hence, the aim of this systematic review is to assess if machine-assisted agitation resulted in less post-operative pain compared with syringe irrigation with needle alone in adult

patients undergoing root canal treatment in mature teeth.

Materials and Methodology

Protocol and registration:

The research protocol is designed according to the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) guidelines 2009. Reference number of registration (PROSPERO CRD42021276823).

Focused question:

Is machine-assisted irrigation activation techniques (intervention) more effective than conventional syringe irrigation (comparator) in reducing post-operative pain (outcome) in patients undergoing endodontic treatment (population)?

Eligibility criteria Inclusion Criteria:

1. Studies that assessed the post-operative pain of at least one machine-assisted irrigation activation technique and one conventional syringe irrigation technique in fully formed permanent teeth of adult patients of varied age groups
2. Studies that had an observation period of at least 4 hours were included.
3. Articles available in the English language.

Exclusion criteria:

1. Book chapters, systematic and literature reviews, proceedings, records, case reports, in vitro studies, and editorials were excluded.
2. Studies that did not assess the post-operative pain of machine-assisted irrigation activation techniques were excluded.
3. Studies that considered agitation techniques other than machine-assisted irrigation were excluded.
4. Studies with multiple dependent variables besides post-endodontic pain.

Study selection:

Titles identified from the search were screened by one reviewer with a subsequent independent checking of their abstracts/full-texts retrieved by the electronic search against the eligibility criteria by another reviewer. Additionally, all references of the selected studies were manually screened for potentially relevant additional studies. Inter-reviewer reliability was assessed with

Cohen kappa (0.80). Any possible discrepancies encountered during this process,

were resolved by discussion between the reviewers who selected the included studies. If a disagreement persisted, the judgment of a third reviewer was considered decisive.

Literature search:

A comprehensive search was conducted on electronic databases, additionally as by manual search, to spot all relevant studies associated with reduction in post-operative pain of machine- assisted irrigation activation and conventional syringe irrigation for endodontic treatments. Electronic databases like PubMed, Science Direct, Cochrane Library, Google Scholar, and Wiley Online were consulted by looking for the keywords like 'endodontic treatment', 'endodontic procedure', 'endodontic therapy', 'root canal treatment', 'machine-assisted irrigation', 'active irrigation device', 'activation device', 'conventional syringe irrigation', 'manual irrigation', 'needle irrigation', 'post-operative pain', 'post-operative discomfort', 'post-endodontic pain', 'post-obturation pain', 'randomized controlled trial', 'clinical trial', 'comparative study'. The combinations of different parameters were used as keywords by using the Google search strategies by applying "AND, NOT, OR" as the conjunctions to get a more refined output for the search. The search lined all articles printed till 2021.

Filters were applied for contemporary research and also articles in the English language. Duplicate records were removed. Also, abstracts only were searched further to full-text articles. The workflow followed the PRISMA checklist.

PICOS Search Strategy Flowchart

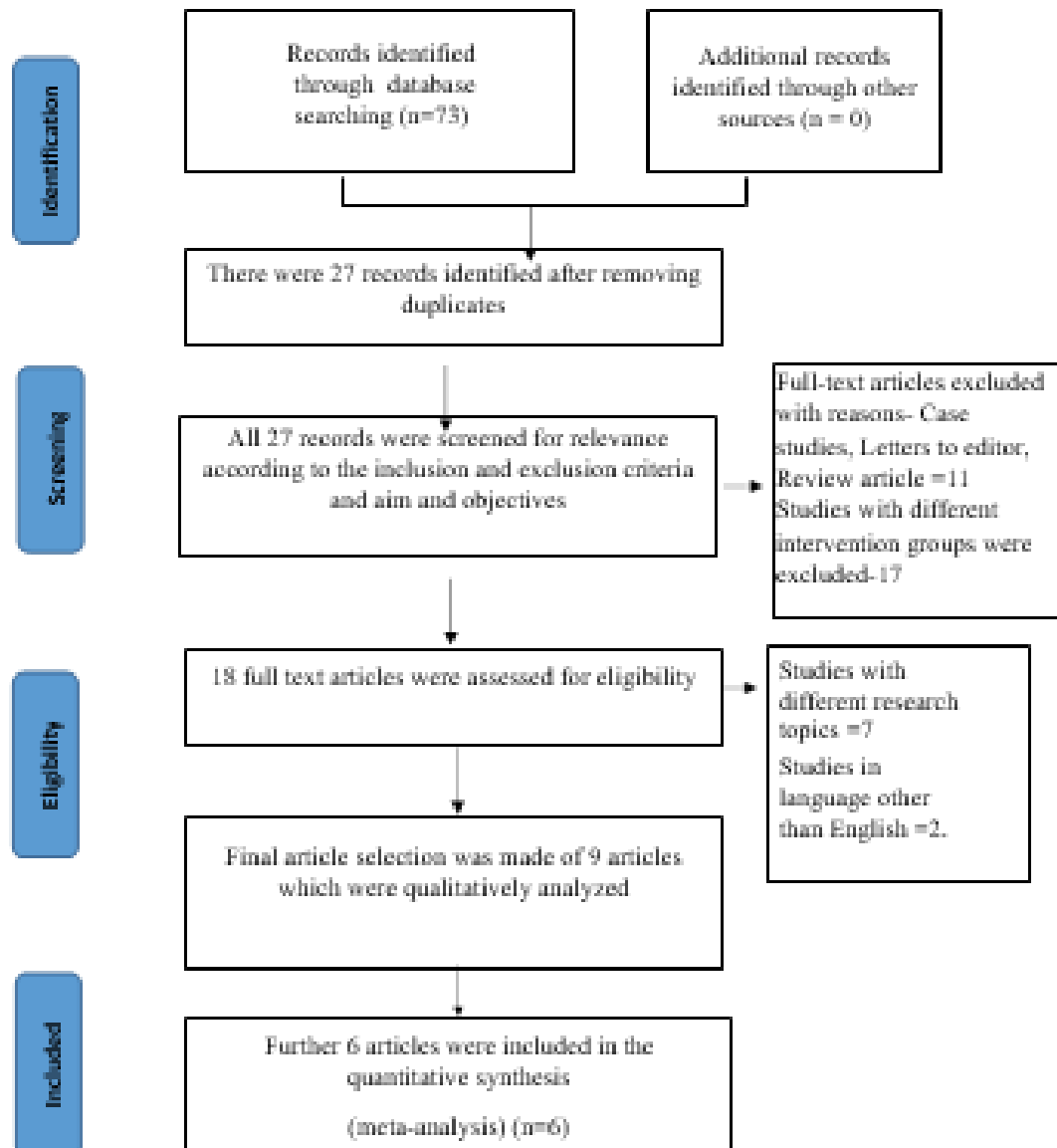


Fig. 1. PRISMA flow chart

Data Extraction and Data Items:

Information on authors' names, year of publications, sample size, number of visits, preoperative pulpal and periapical diagnosis, type of teeth included, groups of intervention, follow-up period, method of irrigation, follow up period, method of pain assessment, and the result was independently extracted by two reviewers. Data regarding the included studies was also independently extracted by the reviewers based on a previously defined protocol in a specific form in the Microsoft Office Excel 2007 software (Microsoft Corporation, Redmond, WA, USA).

Table 2: Characteristics of included studies

Sr.No	Author(Year)	Tooth type	Diagnosis	Irrigant used	Irrigation technique in group 1	Irrigation technique in group 2	Outcome assessment method	Results
1.	Gondim et al. (2010)	Single rooted maxillary and mandibular incisors canines and premolars.	asymptomatic irreversible pulpitis.	5ml of 2.5% NaOCl and 10ml of 17% EDTA was used. 20 ml of NaOCl was used for final wash after EDTA application.	Conventional needle irrigation technique was used.	Use of EndoVac system	Recorded using CR10 Borg list.	Use of negative apical pressure irrigation system Endovac resulted in significantly less post operative pain when compared to conventional needle irrigation system.
2.	Al-Zaka et al. (2012)	Single rooted maxillary and mandibular incisors canines and premolars.	Asymptomatic Irreversible pulpitis	1ml of 2.5% NaOCl for 30 seconds.	Conventional needle irrigation technique was used.	Use of Endoactivator and safety irrigator	Analogue scale questionnaire	The safety irrigator method exhibited significantly lower postoperative pain than the other techniques.
3.	Ramamoorthy et al. (2014)	Multirooted maxillary and	symptomatic irreversible	10ml of 3% NaOCl after	Conventional needle	Use of Endoactivator	VAS scale	Activation of irrigants using

		mandibular teeth.	pulpitis.	each file and then flushed with 2 ml of 17% EDTA solution for 1 min.	irrigation technique was used.			endoactivator resulted in significantly less post operative pain when compared to use of conventional needle irrigation technique.
4.	Tang et al. (2015)	Premolars and molars.	Chronic periapical pulpitis	Use of 2.5% NaOCl	Conventional needle irrigation technique was used.	Use of Ultrasonic irrigation technique	VAS scale	The post - operative pain was significantly lower in the ultrasonic group when compared to use of conventional needle irrigation technique.
5.	Middha et al (2017)	Mandibular molar teeth.	Non - vital pulp and radiographic evidence of apical periodontitis.	Use of 20ml 2.5% NaOCl followed by final rinse of 5ml of 17% EDTA followed by 5 ml of distilled water.	Conventional needle irrigation technique was used.	Continuous ultrasonic irrigation.	VAS scale	Use of negative apical irrigation device resulted in reduction in post operative pain compared to conventional

								needle Irrigation.
6.	Topcuoğlu et al (2018a)	Mandibular molar teeth.	symptomatic irreversible pulpitis	20ml of 2.5% NaOCl placed 2mm short of working length followed by final rinse of 5ml of 17% EDTA and 5ml of distilled water,	Conventional needle irrigation technique was used.	Use of EndoVac system.	VAS scale	Apical positive pressure irrigation caused greater post operative pain compared to apical negative pressure irrigation.
7.	Topcuoğlu et al (2018b)	Mandibular molar teeth.	symptomatic irreversible pulpitis	20ml of 2.5% NaOCl placed 2mm short of working length followed by final rinse of 5ml of 17% EDTA and 5ml of distilled water,	Conventional needle irrigation technique was used.	Use of EndoVac system.	VAS scale	Apical positive pressure irrigation caused greater post operative pain compared to apical negative pressure irrigation.
8.	Yilmaz et al. 2019	Mandibular molar teeth.	Non - vital pulp	Use of 10 ml of 2.5% NaOCl .	Conventional needle irrigation technique was used.	Use of Endoactivator	VAS scale	Activation of irrigants using endoactivator resulted in significantly less post operative pain when

								compared to use of conventional needle irrigation technique.
9.	Vishwakarma et al (2020)	mature permanent upper and lower molar	Symptomatic Irreversible pulpitis	Use of 4ml 2.5% NaOCl	Conventional needle irrigation technique was used.	Use of Endoactivator	VAS scale	Use of negative Apical irrigation device resulted reduction in post operative pain compared to conventional needle irrigation.

Risk Of Bias Within Studies:

The risk of bias within the studies was evaluated independently by two review researchers. The studies were classified as low risk of bias, unclear, and high-risk bias (9). The following domains were assessed.

Table 2: Risk of bias for included studies

Study	Random assignment of respondents into groups	Concealment of randomization sequence	Blinding	Selective outcome data	Complete reporting of outcomes	Other bias sources	The overall risk of bias
<u>Gondim et al. 2010</u>	Yes	Yes	Yes	Yes	Yes	Yes	Low
<u>Al-Zaka et al. (2012)</u>	Unclear	Yes	Yes	Yes	Yes	Yes	Uncertain
<u>Ramamoorthy et al. (2014)</u>	Yes	Yes	Yes	Yes	Yes	Yes	Low
<u>Tang et al. (2015)</u>	No	No	No	Yes	Yes	Yes	High
<u>Middha et al. (2017)</u>	Yes	Yes	Unclear	Yes	Yes	Yes	Uncertain
<u>Topcuoglu et al. (2018a)</u>	Yes	Unclear	Yes	Yes	Yes	Yes	Uncertain
<u>Topcuoglu et al. (2018b)</u>	Yes	Unclear	Yes	Yes	Yes	Yes	Uncertain
<u>Yilmaz et al. (2019)</u>	Yes	Yes	Yes	Yes	Yes	Yes	Low
<u>Vishwakarma and Shenoy (2020)</u>	Yes	Yes	No	Yes	Yes	Yes	High

Results

Study characteristics

Nine articles (10,11,12,13,14,15,16,17,18,) were selected after screening of the above- mentioned number of articles by two independent reviewers. Following careful examination, each data parameter related to the study or the selection criteria was discussed by the reviewers. Any discrepancies in opinion were resolved by the third reviewer. The studies that did not meet the inclusion criteria were excluded. Ultimately nine articles were finalized for qualitative synthesis. The studies included in the review were performed between 2010 and 2020.

All the studies were randomized control studies performed on adult patients with ages ranging from 18-65 years. The preoperative periapical status assessment revealed two studies(13,14) that included teeth with both apical periodontitis. Root canal treatments were performed in a single visit in six studies and two visits in one study. Tooth type when assessed revealed one study(13) included both multirrooted and single-rooted teeth, while two studies (12,18) included only molars and four studies (14-17) included only mandibular molars, while two studies (10,11) included only single-rooted teeth. Machine-assisted activation devices like

ultrasonic, sonic devices, and negative apical pressure devices were used as an intervention group in all the nine studies included in this systematic review. Three studies (10,15,16) included the use of negative apical pressure devices like EndoVac, sonic activated devices like Endoactivator were used in four studies (11,12,17,18) and ultrasonic irrigation technique was used in two studies. These methods of machine-assisted irrigation techniques were assessed against conventional needle syringe irrigation techniques in assessing postoperative endodontic pain Follow-up of postoperative pain ranged from 8hrs to 72 hours and was recorded using a visual analog scale (VAS).

The meta-analysis was performed on 6 studies((12,14,15,16,17,18) that have qualified with the required data outcome that could be analysed quantitatively. The results of the overall comparison have been depicted as a forest plot. With the meta-analysis conducted for selected studies, heterogeneity was less than 50% ($I^2 = 43\%$); hence, the fixed effect model was applied. VAS score was less machine-assisted irrigation group as compared to standard needle irrigation group, with a mean difference of -0.34 (95% CI = -0.49 to -0.18; Z value = 4.24). This difference in VAS score among the two groups was statistically significant ($p=0.001$).

Fig.2 Forest Plot

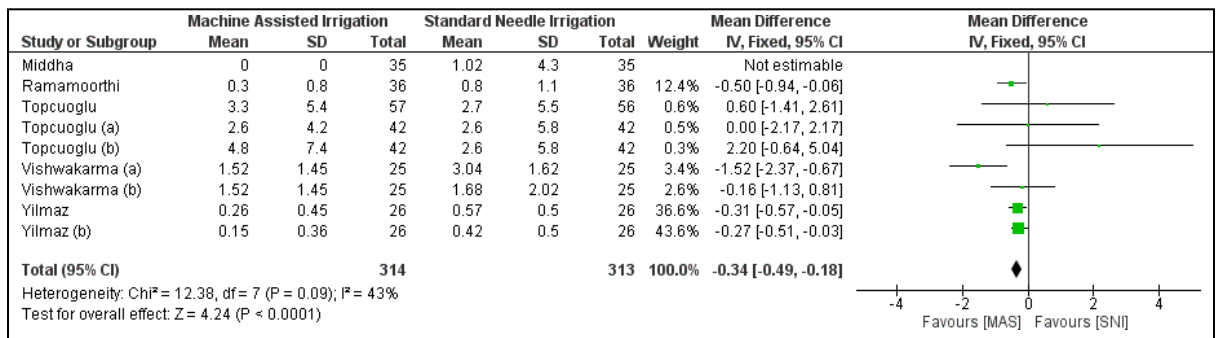


Fig 3: Forest plot of comparison: Time interval, outcome: 8 hours

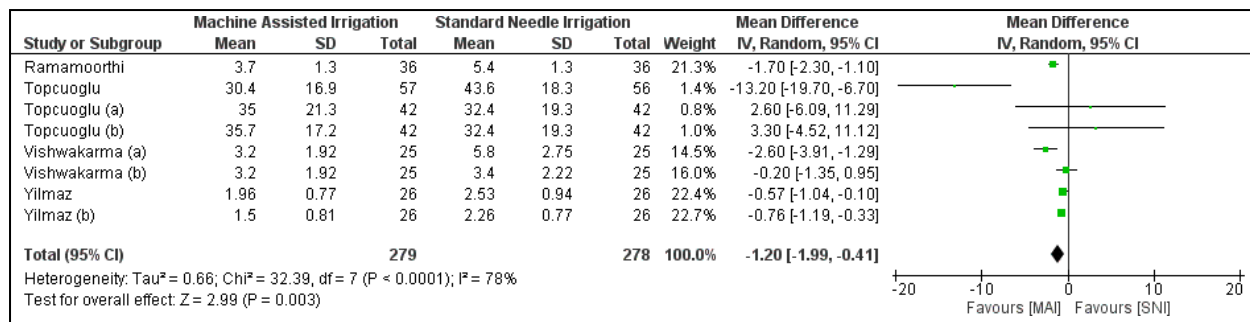


Fig 4: Forest plot of comparison: Time interval, outcome: 24 hours

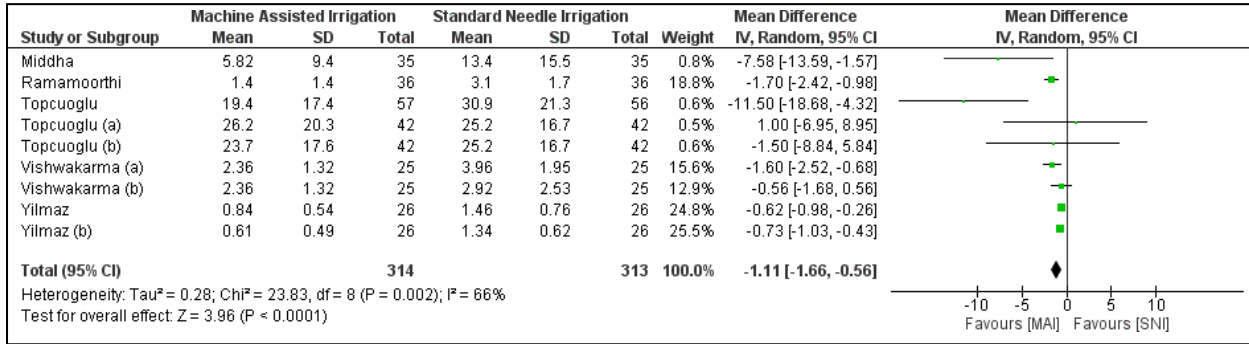


Fig 5: Forest plot of comparison: Time interval, outcome: 48 hours

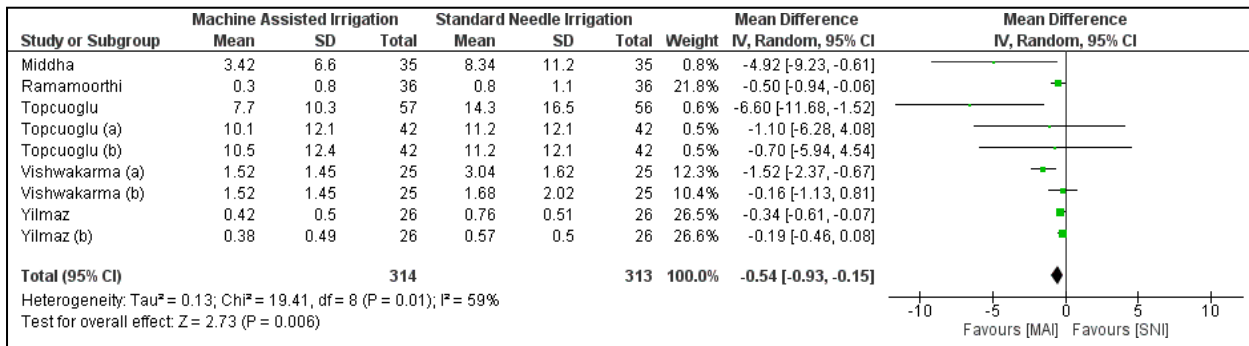
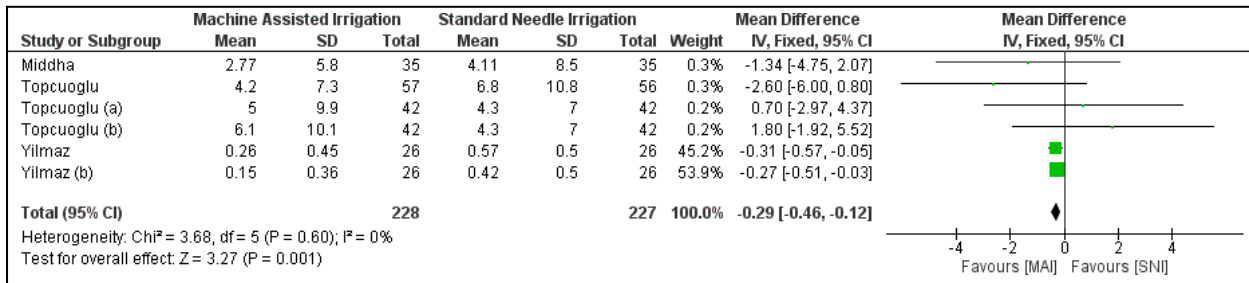


Fig 6: Forest plot of comparison: Time interval, outcome: 72 hours



Comparisons of VAS score was done after 8 hours, 24 hours, 48 hours and 72 hours using the mean difference (MD) for VAS score between Standard Needle Irrigation and Machine assisted Irrigation. VAS score was less in the machine-assisted irrigation group as compared to the Standard Needle Irrigation group, with a mean difference of -0.34. This difference in VAS score among the two groups was statistically significant in all the four-time intervals, thus statistically proving the effectiveness of machine-assisted irrigation in reducing pain as compared to conventional needle irrigation.

Risk of bias

The methodological quality of all the studies was done using the risk-of-bias assessment tool as elaborated in Cochrane Handbook for Systematic Review of Interventions (version 5.1.0) [Higgins JPT, Green S, editors. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. The

Cochrane Collaboration; 2011. Available at: <http://www.cochrane-handbook.org>]. The results are presented in Figure 7 & 8 as the risk of bias graph and summary respectively which was generated using the RevMan software (v5.3). There are six domains under which the methodology of individual studies is assessed and granted a level of risk. The quality assessment of included 9 studies was done with representation (Figure 7 & 8). One study was excluded for the assessment due to a contradiction in the study design (Jaiswal et al). All the studies showed either unclear allocation concealment or no mention of blinding of participants or the outcome assessed.

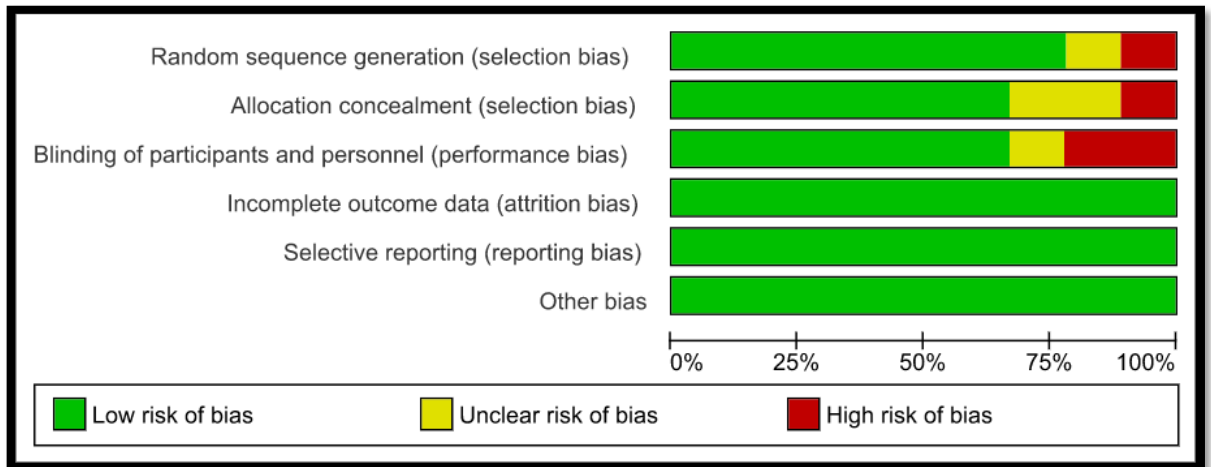


Fig. 7: Risk of Bias Assessment

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
al-Zaka et al 2012	?	+	+	+	+	+
Gondim et al 2010	+	+	+	+	+	+
Midha et al 2017	+	+	?	+	+	+
Ramamoorthy et al 2014	+	+	+	+	+	+
Tang et al 2015	-	-	-	+	+	+
Topcuoglu et al I 2018	+	?	+	+	+	+
Topcuoglu et al II 2018	+	?	+	+	+	+
Vishwakarma and Shenoy 2020	+	+	-	+	+	+
Yilmaz et al 2019	+	+	+	+	+	+

Fig.8 Risk Assessment Table

Discussion

The post-operative pain control is multifactorial in its etiology and is the most important consideration for the patient and hence to the clinician both during and after root canal treatment. Since endodontic pain management is centered around complete debridement and disinfection of the root canal system, the significance of irrigation and irrigating agents becomes more crucial due to anatomic variations and complexities of the root canal system.(19) The performance of manual irrigation and manual dynamic activation has limitations owing to its inability to deliver the irrigant into all the parts of the complicated root canal system.(20) Machine assisted irrigation techniques include sonics and ultrasonics, as well as newer systems such as the EndoVac, based on apical negative pressure; the GentleWave, based on multisonic pressure wave formation; the Vibringe (Vibringe); and the EndoActivator based on sonic vibrations.(21) Activation of irrigants via sonic and ultrasonic devices has shown great improvement in the cleaning and disinfection of the root canal system and should be considered an

important fundamental step in non-surgical endodontic therapy.(22)

Number of studies have been performed to evaluate the effectiveness of different irrigation techniques in reducing the postoperative pain, however, a systematic analysis of the quality

of these randomized controlled trials needs to be evaluated using well defined criteria like those used in the risk of bias assessment.

Thus, a systematic review is a viable way of analyzing the effectiveness of various methods of irrigation activation techniques in reducing postoperative pain. The present systematic review aimed to compare the effect of machine-assisted and syringe irrigation with needles on post-operative pain. The component studies included ultrasonic or sonic devices and negative apical pressure devices as agitation techniques as intervention group.

It has been stated that variables such as age, gender, psychological factors contribute to the perception of pain by the patients. In contrast, three studies showed that there were no significant differences between sex, age distribution, and baseline pain scores between the two groups owing to adequate sample size; therefore, the effects of these variables were minimized.

Out of the nine randomized clinical trials (10,11,12,13,14,15,16,17,18) reviewed for this systematic review, five studies (10,11,13,14,17) included asymptomatic teeth and another four studies (12,15,16,18) included symptomatic teeth. In the five studies (10,11,13,14,17) that assessed asymptomatic teeth, greater reduction of post operative pain was observed, thus presence of preoperative symptoms is considered an important confounding factor among the studies.

In the randomized clinical trial by Gondim et al (10) and Al Zaka et al(11), only teeth with single canal were incorporated to reduce the confounding effect of complex root canal anatomy, to minimize the risk of iatrogenic errors because of missed or complicated root canal anatomy and to make sure the same amount of irrigation solution would pass by each canal. Thus, inclusion of single rooted anterior teeth and multirrooted posterior teeth need to be evaluated separately.

Post-operative pain after single visit endodontics has been shown to be less than multivisit endodontic treatment according to the studies done by Su et al. and Albashaireh et al. (23,24)Hence, in the studies done by Gondim et al and Al Zaka et al(10,11), all teeth were instrumented and obturated in one session to eliminate intracanal medication as another possible factor for postoperative flareup. One of the study(12) had performed multi visit endodontic treatment as it offers numerous advantages like complete eradication of microorganisms; using calcium hydroxide, it could re-evaluate the tissue responses, but its disadvantages include, prolonged number of visits, interappointment flare ups, and patient fatigue. Hence, inclusion of this criteria in the factors contributing to post- operative pain is important. Mechanical irrigation was found to have less post -operative pain irrespective of the number of visits required for the endodontic treatment completion.

Preoperative administration of drugs might have an effect to suppress or reduce post endodontic pain.(25) Thus, only patients without a contributing medical history who did not take analgesic medication recently were included in three studies. Three out of nine studies (10,11,12,13,14,15,16,17,18) only have included patients without a non-contributing history who did not take analgesic medication recently. The rest of the studies did not include this as the criteria and hence would contribute to reporting bias.

Conventional irrigation with syringes has been advocated as an easy and hence most commonly used method of irrigant delivery. This technique is still widely accepted by both general practitioners and endodontists with modified irrigating tips such as side vented, perforated, large gauge finer needles. The precautions taken while using needle and syringe for irrigation are 1) Continuous up- down movement of the needle tip 2) Prevention of wedging of the tip of the needle 3) 2-3 mm away from the apex.(26) These precautions have been taken and are mentioned in all the nine studies for standardization of the study design of the randomized clinical trials included in the systematic review.

Brown DC et al (27) and Mitchell RP et al(28) have stated that positive pressure irrigation may extrude irrigants into the periapical tissue that results in postoperative pain. This could be the possible reason for the results obtained by all the nine review studies for irrigation included in this systematic review employing conventional needle syringe as their control group.

All the nine studies included in this systematic review had at least one machine assisted activation device like ultrasonic, sonic devices or negative apical pressure device. Three studies(10,15,16) included the use of negative apical pressure devices like EndoVac; four studies(11,12,17,18) employed sonic activated devices like Endoactivator and two studies (13,14) used ultrasonic device for irrigation activation. All the studies found that post operative pain is lesser than the conventional manual irrigation. Romualdo et al(29) , also reported that the irrigation method using apical negative pressure prevents the apical extrusion of the irrigant compared with methods using positive pressure. Studies done by Al Zaka et al (11), Ramamoorthy et al(12), Yilmaz et al(17) and Vishwakarma et al(18) have found significant difference in the postoperative pain by the use of sonic activated devices like Endoactivator. Ultrasonic irrigation has been demonstrated to enhance delivery of irrigants to uninstrumented areas of root canal system and help remove remaining debris and bacteria by inducing acoustic streaming and cavitation of the irrigant.(30) Studies by Gutarts and Burleson et al(31) have shown that the one minute of continuous ultrasonic irrigation after hand or rotary instrumentation improved the cleanliness of canals and isthmi and reduced microbial load.

Limitations

The variability among the studies with respect to the method of different machine assisted irrigation devices against the use of conventional irrigation technique, and the different volumes used could be seen as a limitation. Presence of a number of confounding factors, which were difficult to control in the studies, make it difficult to attribute pain to only one factor. Additionally, trauma due to rubber

dam isolation or to soft tissue caused by anaesthetic injection alters the perception of the pain. Although, instrumentation was performed meticulously, there are always chances of apical extrusion of debris which will be impossible to detect in an in vivo study model. The VAS score results may not be true representation of pain control as effect of analgesics was not excluded.

Future Studies

Currently, there is limited research to recommend a specific irrigation activation method, flow rate, specific agitation regimen, volume of irrigant required and ranges of apical pressures within the root canal system. Thus, the importance of standardizing variables is to be taken into consideration in future studies in order to eliminate potential confounding factors and allow the analysis of these factors individually and its impact on accurate assessment of postoperative pain.

Conclusion

Within the limitations of the present study, it can be concluded that machine-assisted irrigation was more effective than conventional syringe irrigation in reducing postoperative pain at 8, 24, 48, 72 hours. This systematic review of nine studies and meta - analysis of six studies confirmed the same as depicted in the forest plot and hence should be considered as an important fundamental step for management of postoperative pain in non-surgical endodontic therapy.

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3. Authors' contributions-

All authors have contributed significantly, and all authors are in agreement with the manuscript.

Name	Concept and design	Acquisition of data or analysis	Interpretation of data	Drafting the article	Final approval
Dr Vibha Hegde	✓	✓			✓
Dr Mrunalini Vaidya	✓	✓		✓	✓
Dr Simren Bhatia	✓	✓	✓	✓	
Dr Surelee Chavan	✓	✓	✓	✓	

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