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## Healing of Apical Periodontitis after Gentle Wave System Versus Ultrasonic Activation with Negative Pressure Irrigation: A Systematic Review and Meta-analysis

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### ABSTRACT

**Background and aim:** The use of modern methods for root canal disinfection and the improvement of apical periodontitis are of great importance. Therefore, the present Systematic Review and Meta-Analysis was conducted to investigate the Healing of Apical Periodontitis after the Gentle Wave System versus Ultrasonic Activation with Negative Pressure Irrigation.

**Materials and methods:** The international databases PubMed/Scopus, MEDLINE (Ovid), Cochrane Library, and Embase were searched using keywords aligned with the study objective, up to August 2025. Two blinded, independent authors reviewed all articles. STATA/MP.v17 (College Station, Texas, USA) was used to perform the analyses.

**Results:** Based on the findings of 12 included studies, healing rates for Gentle Wave System was 97% (ES: 97% 95% CI= 95%, 99%; p=0.51; I2=0); the healing rates for Ultrasonic Activation was 77% (ES: 77% 95% CI=75%, 79%; p=0.01; I2=62.88); the healing rates for Negative Pressure Irrigation. was 82% (ES: 82% 95% CI=79%, 85%; p=0.05; I2=60.79). There was a statistically significant difference in healing rates among the groups, with the Gentle Wave System performing significantly better than both Negative Pressure Irrigation and Ultrasonic Activation (p < 0.001).

**Conclusions:** Based on the present meta-analysis, the Gentle Wave System was found to be more effective than Negative Pressure Irrigation and Ultrasonic Activation in improving apical periodontitis.

### 1. Introduction

According to statistics, more than 25 million root canal procedures are performed annually to treat inflamed or infected dental pulps, reduce pain, and restore the health and function of teeth.<sup>[1]</sup> Root canal therapy is performed to fill root canals, clean the root canal system, remove infected pulp, and restore the tooth.<sup>[2]</sup> The most widely used disinfectant is sodium hypochlorite (NaOCl), which has antimicrobial and anti-biofilm properties. However, it has been reported to be ineffective in removing mineralized tissues; therefore, it is recommended to use 17% ethylenediaminetetraacetic acid (EDTA).<sup>[3]</sup> Evidence suggests that, regardless of the power of the irrigating solution, if it cannot penetrate the apical part of the root canal, it will not yield good results.<sup>[4]</sup> Conventional syringe irrigation (CSI) has been routinely used to deliver irrigation solutions into the root canal; however, studies have shown that this method may not reach the working length (WL) and root canal.<sup>[5, 6]</sup>

the irrigation solution may even exit the root canal.<sup>[7]</sup> Therefore, new methods have been introduced, including ultrasonic activation (UA), negative pressure irrigation (NPI), and XP-Endo Finisher instruments.<sup>[8, 9]</sup> The findings of the studies indicate that NPI provides better penetration into the WL.<sup>[10]</sup> It also provides more effective washing and reduces the Number of bacteria compared to the traditional method.<sup>[11]</sup> UA has also been reported as an effective method that provides the ability to wash a wider area by creating an acoustic flow.<sup>[12]</sup> An emerging technology that can be highly effective in disinfecting the root canal system and reducing bacterial growth is the GentleWave (GW) multisonic ultracleaning system. In vitro studies have demonstrated that biofilm removal using this method is highly significant, and the high efficiency of pulp tissue dissolution has made it popular.<sup>[13-15]</sup> Very few studies have examined the effectiveness of GW in combination with other

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modern methods; furthermore, there is insufficient scientific evidence to determine the superiority of any method. The findings of the studies are scattered and contradictory, and a consensus has not yet been reached. Choosing an effective method for cleaning the root canal and increasing the treatment success rate is challenging and of great importance. Also, the use of modern, high-performance methods can reduce treatment costs and improve patients' quality of life by preserving natural teeth. This meta-analysis study is the first to compare the effectiveness of the Gentle Wave system and the negative pressure ultrasonic method, providing strong scientific and clinical evidence. The results of the present study can help dentists make evidence-based decisions when choosing an effective method for root canal cleaning and treating apical periodontitis. Therefore, the present study was conducted to determine the effectiveness of GW and UA compared to NPI in improving apical periodontitis.

## 2. Material and methods

### Search strategy

The present study was designed and conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)

guidelines.<sup>[16]</sup> A search was conducted in the international databases PubMed/Scopus, MEDLINE (Ovid), Cochrane Library, and Embase using relevant keywords (Table 1) as of August 2025. References of articles were also reviewed to find similar studies. Each English-language article was considered. Two independent, blinded authors conducted separate literature searches and retrieved titles, abstracts, and full texts of relevant studies.

### Selection criteria

Included criteria: Studies were included if they met the PICOS strategy criteria. Population (P): Teeth with Apical Periodontitis; Intervention (I): GW; (C): Non-GW OR single-arm GentleWave; Outcome (O): Healing Outcomes; S (Study): cohort study, and randomized controlled trial (RCT) studies.

Exclusion criteria: (1) reviews, in vivo studies, case reports, Observational and descriptive studies, studies without control groups, and literature that is unavailable or incomplete; (2) studies that do not involve human subjects; and (3) articles written in a language other than English.

Table 1. Search Strategy.

| International Databases | Search Strategy  |
|-------------------------|--|
|                         | Disease: Apical Periodontitis  |
|                         | #1   Apical Periodontitis #1 "Apical Periodontitis"[Mesh] OR "Periapical Disease" OR "Periapical Lesion" OR "Periapical Healing" OR "Endodontic Infection*" OR "Root Canal Infection"  |
|                         | Intervention: GentleWave or Ultrasonic Activation  |
|                         | #2   "GentleWave System" OR "Gentle Wave" OR "Multisonic Ultracleaning" AND Ultrasonic Activation"   |
| PubMed                  | Comparator: Negative Pressure  |
|                         | #3   Negative Pressure Irrigation" OR "EndoVac" OR "Apical Negative Pressure"  |
|                         | Context  |
|                         | #4   root Canal Therapy"[Mesh] OR "Root Canal Irrigation" OR "Endodontic Treatment*" OR Endodontics.   |
|                         | #5   #4 AND #1 AND #2 AND #3   |
| Embase                  | 'apical periodontitis'/exp OR 'periapical disease' OR 'periapical lesion' OR 'root canal infection*' OR 'endodontic infection'<br>'gentlewave system' OR 'gentle wave' OR 'multisonic ultracleaning'<br>'ultrasonic activation' OR 'passive ultrasonic irrigation' OR 'pui' OR 'ultrasonic irrigant activation'<br>'negative pressure irrigation' OR 'endovac' OR 'apical negative pressure'<br>'root canal therapy'/exp OR 'root canal irrigation' OR 'endodontic treatment*' OR endodontics.                           |
| MEDLINE (Ovid)          | Apical Periodontitis/ OR Periapical Disease/ OR Periapical Lesion*.mp. OR Endodontic Infection*.mp. OR Root Canal Infection*.mp.<br>GentleWave System.mp. OR Gentle Wave.mp. OR Multisonic Ultracleaning.mp.<br>Ultrasonic Activation.mp. OR Passive Ultrasonic Irrigation.mp. OR PUI.mp. OR Ultrasonic Irrigant Activation.mp.<br>. Negative Pressure Irrigation.mp. OR EndoVac.mp. OR Apical Negative Pressure.mp.<br>Root Canal Therapy/ OR Root Canal Irrigation.mp. OR Endodontic Treatment*.mp. OR Endodontics.mp. |
|                         | Disease: Apical Periodontitis  |
|                         | #1   MeSH descriptor: [Apical Periodontitis] explode all trees.  |
| Cochrane Library        | #2   ("Periapical Disease*" OR "Periapical Lesion*" OR "Endodontic Infection*" OR "Root Canal Infection*"):ti,ab,kw.   |
|                         | #3   |
|                         | Intervention: GentleWave   |

|    |  |
|----|--|
| #3 | ("GentleWave System" OR "Gentle Wave" OR "Multisonic Ultracleaning"):ti,ab,kw<br>Ultrasonic Activation:ti,ab,kw. |
| #4 | "Passive Ultrasonic Irrigation" OR PUI OR "Ultrasonic Irrigant Activation"):ti,ab,kw.                            |
| #5 | ("Negative Pressure Irrigation" OR "EndoVac" OR "Apical Negative Pressure"):ti,ab,kw.                            |
| #6 | ("Root Canal Therapy" OR "Root Canal Irrigation" OR "Endodontic Treatment*" OR<br>Endodontics):ti,ab,kw.         |
| #7 | #6 #1 OR #2 AND (#3 OR (#4 AND #5)) AND #6   |

### Data extraction

Data from each included study were independently and blindly extracted by two investigators using a standard data extraction form; disagreements between the investigators were discussed and resolved by a third reviewer. In a nutshell, the study's attributes include the name of the first author, the year of publication, the Number of populations, the Mean age, the Gender, the Pulpal diagnosis, the Periapical diagnosis, and the tooth type.

### Quality assessment

Two authors independently assessed the quality of the studies. The Newcastle-Ottawa Scale (NOS) was used to assess the quality of the included studies for cohort studies,<sup>[17]</sup> and Version 2 of the Cochrane risk-of-bias tool for randomized trials (RoB 2) was used for RCT studies.<sup>[18]</sup> Three criteria (selection, comparability, and outcomes) were considered in the NOS tool, and three criteria (trial design, conduct, and reporting) were considered in the Rob2 tool. The NOS tool is scored from zero to nine (0-3, 4-6, and 7-9), and the Rob2 tool is scored from zero to six (0-2, 3-4, 5-6). Scores of 7-9 for NOS and 5-6 for Rob2 indicate a low risk of bias.

### Statistical analysis

Statistical analysis was performed with STATA/MP.v17 (College Station, Texas, USA) software. Heterogeneity was assessed using the  $I^2$  statistic (No heterogeneity:  $0.0\% < I^2 < 24.9\%$ ; low heterogeneity:  $25.0\% < I^2 < 49.9\%$ ; Moderate heterogeneity:  $50.0\% < I^2 < 74.9\%$ ; High heterogeneity:  $75.0\% < I^2 < 100\%$ ), and in the presence of high heterogeneity, a fixed-effects and random effect model with Inverse-variance and REML method used for effect size with 95% CI. Publication bias was assessed using Egger's test and funnel plot.

## 3. Results

### Literature search

In the initial search using keywords, 359 articles were identified. After reviewing the titles, duplicate articles were removed, and 113 articles were excluded from the review due to their study type. In the next step, the abstracts of 246 articles were evaluated according to the inclusion and exclusion criteria, and another 192 articles were excluded. Finally, the full text of 54 articles was reviewed independently by two authors without knowledge of each other's opinions. In cases of disagreement, the opinion of the third author was applied. After this process, 12 articles that were consistent with the study objectives were selected for analysis.

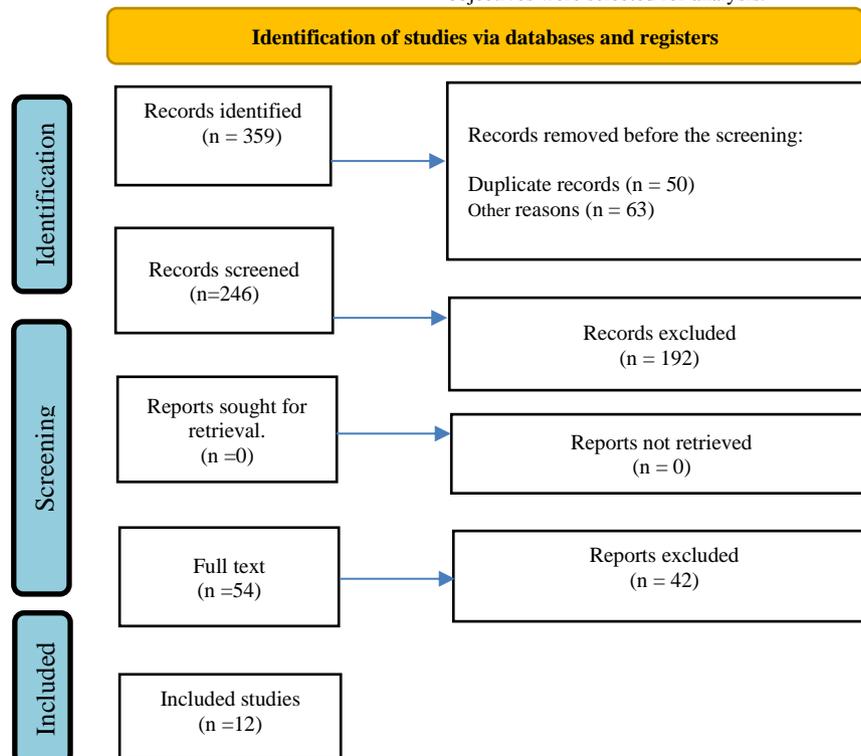


Fig. 1. Flowchart of PRISMA 2020 and selection of studies.

### Study Characteristics

In the present study, twelve articles from randomized controlled trials (RCTs) and prospective clinical studies (PCSs) published between 2013 and 2025 were included. The sample size was estimated to be 826 patients, and all studies included both male and female patients. The recall rate in the studies ranged from 67% to 97.8%. The interventions investigated included GW, UA, and NPI as methods for root canal disinfection. Healing of apical

periodontitis was assessed at follow-up periods ranging from 6 to 24 months. The majority of treated teeth were maxillary and mandibular molars, although some studies also included single-rooted mandibular teeth, maxillary central incisors, and periapical cystic-like lesions (Table 2).

### Bias assessment

The risk of bias for all studies was considered moderate (Table 2).

Table 2. Characteristics of Patients from included studies.

| No. | Variable | Study Design | Study/Year                                    | Number of Patients |      | Recall Rate | Healing | Type of Tooth  | Follow-up (Months) | Bias Assessment |
|-----|----------|--------------|---|--------------------|------|-------------|---------|--|--------------------|-----------------|
|     |          |              |   | Female             | Male |             |         |  |                    |                 |
| 1   | GW       | PCS          | Montero et al., 2025 <sup>[19]</sup>          | 45                 | 40   | 77%         | 89%     | Maxillary and mandibular molars                          | 12                 | 6/9             |
|     | UA       |              |   | 23                 | 20   |             | 72.9%   |  |                    |                 |
|     | NPI      |              |   | 23                 | 19   |             | 70.6%   |  |                    |                 |
| 2   | UA       | RCT          | Kwon et al., 2025 <sup>[20]</sup>             | 125                |      | 80.4%       | 84.8%   | Maxillary and mandibular molars                          | 12                 | 3/6             |
| 3   | NPI      | PCS          | Talpoş-Niculescu et al., 2025 <sup>[21]</sup> | 6                  | 4    | NR          | 85%     | Periapical Cystic-Like Lesions                           | 12, 24             | 5/9             |
| 4   | NPI      | PCS          | Ling et al., 2024 <sup>[22]</sup>             | 19                 | 16   | 83%         | 77%     | Maxillary and mandibular molars, incisors, and premolars | 12                 | 5/9             |
| 5   | UA       | RCT          | Doğan et al., 2024 <sup>[23]</sup>            | 56                 |      | 89%         | 67%     | mandibular single-rooted tooth                           | 12                 | 3/6             |
| 6   | UA       | RCT          | Arikan et al., 2024 <sup>[24]</sup>           | 70                 |      | 94%         | 77%     |  | 12                 | 4/6             |
| 7   | NPI      | PCS          | Alaa et al., 2023 <sup>[25]</sup>             | 17                 |      | NR          | 84%     | maxillary central incisors                               | 12                 | 6/9             |
|     | UA       | PCS          |   | 17                 |      | NR          | 79%     |  |                    |                 |
| 8   | UA       | RCT          | Verma et al., 2020 <sup>[26]</sup>            | 23                 |      | 89%         | 68.4%   | Maxillary and mandibular molars                          | 12                 | 4/6             |
| 9   | GW       | PCS          | Sigurdsson et al., 2018 <sup>[27]</sup>       | 21                 | 24   | 97.8%       | 97.7%   | Maxillary and mandibular molars                          | 12                 | 5/9             |
| 10  | GW       | PCS          | Sigurdsson et al., 2016 <sup>[28]</sup>       | 51                 | 38   | NR          | 97.3    | Maxillary and mandibular molars                          | 6                  | 6/9             |
| 11  | GW       | PCS          | Sigurdsson et al., 2016 <sup>[29]</sup>       | 50                 | 39   | NR          | 97.7%   | Maxillary and mandibular molars                          | 12                 | 6/9             |
| 12  | UA       | RCT          | Liang et al., 2013 <sup>[30]</sup>            | 25                 | 25   | 82%         | 72.6%   | Single-rooted teeth                                      | 12                 | 3/6             |

### Healing rates

The subgroup meta-analysis (Figure 2) showed the healing rates for GW system was 97% (ES: 97% 95% CI= 95%, 99%;  $p=0.51$ ;  $I^2=0$ ); the healing rates for UA was 77% (ES: 77% 95% CI=75%, 79%;  $p=0.01$ ;  $I^2=62.88$ ); the healing rates for NPI was 82% (ES: 82% 95% CI=79%, 85%;  $p=0.05$ ;  $I^2=60.79$ ).

According to the test of group differences, there was a statistically significant difference in healing rates among the groups, with the GW system performing significantly better than both NPI and UA ( $p < 0.001$ ).

### Recall rate

The subgroup meta-analysis of recall rates at 12 months (Fig. 3) showed the recall rate for GW system was 87% (ES: 87% 95% CI= 68%, 100%;

$p=0.01$ ;  $I^2=86.96$ ); the recall rate for UA was 85% (ES: 77% 95% CI=75%, 79%;  $p=0.01$ ;  $I^2=66.06$ ); the recall rate for NPI was 82% (ES: 82% 95% CI=77%, 87%;  $p=0.37$ ;  $I^2=0$ ).

The test for group differences revealed no statistically significant difference among the three groups in recall rate at 12 months ( $p < 0.001$ ).

Funnel plots (Fig. 4) showed in the GW system group, the spots were nearly symmetrical, indicating a lack of evidence of propagation bias. In the NPI group, the points were relatively symmetrical, but given the small Number of studies, definitive conclusions are limited; the likelihood of bias in this group appears low. For UA, the Funnel Plot is slightly asymmetrical, with some points lying to the left or below the midline, suggesting the possibility of publication bias or a small effect of heterogeneity.

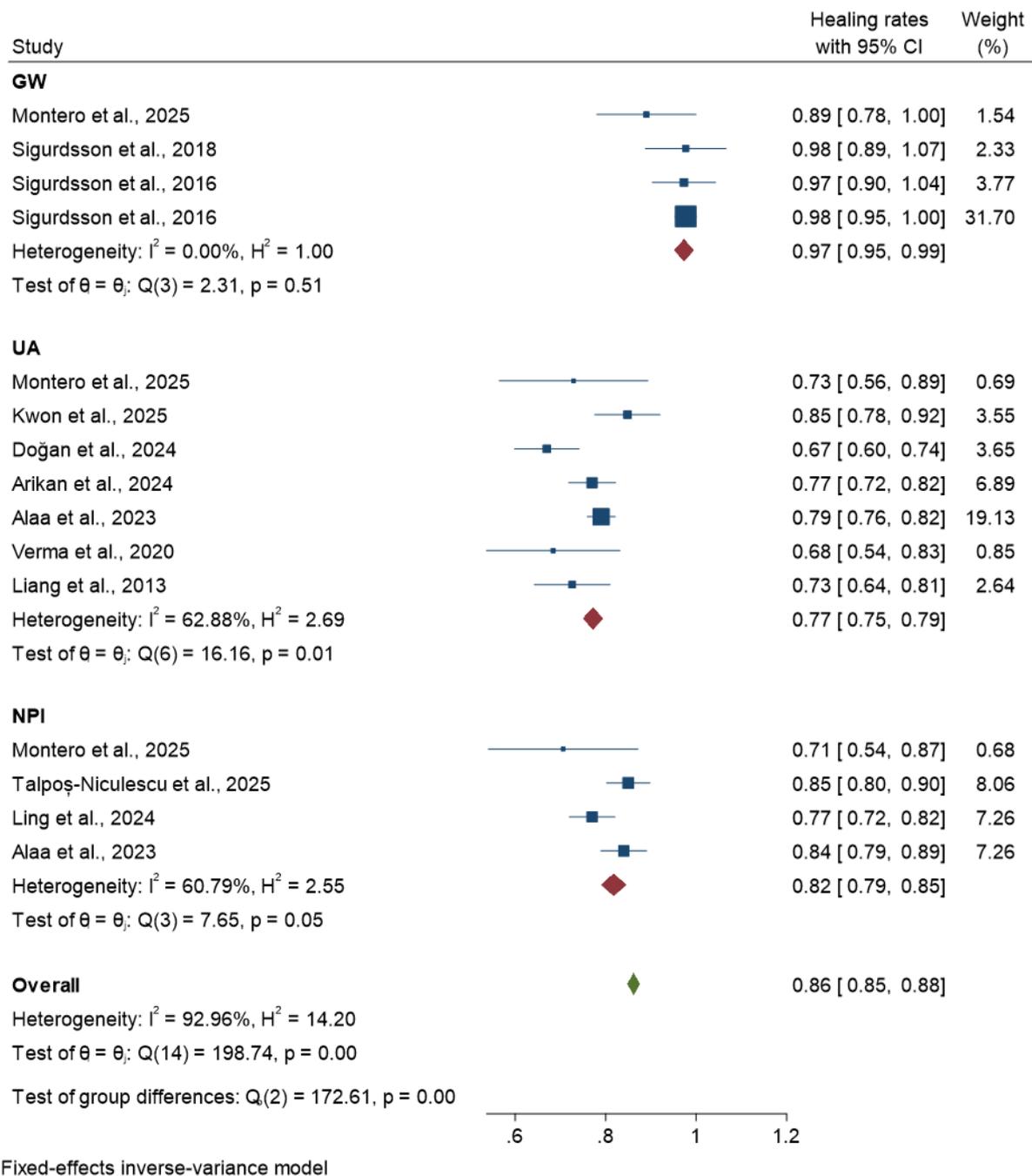
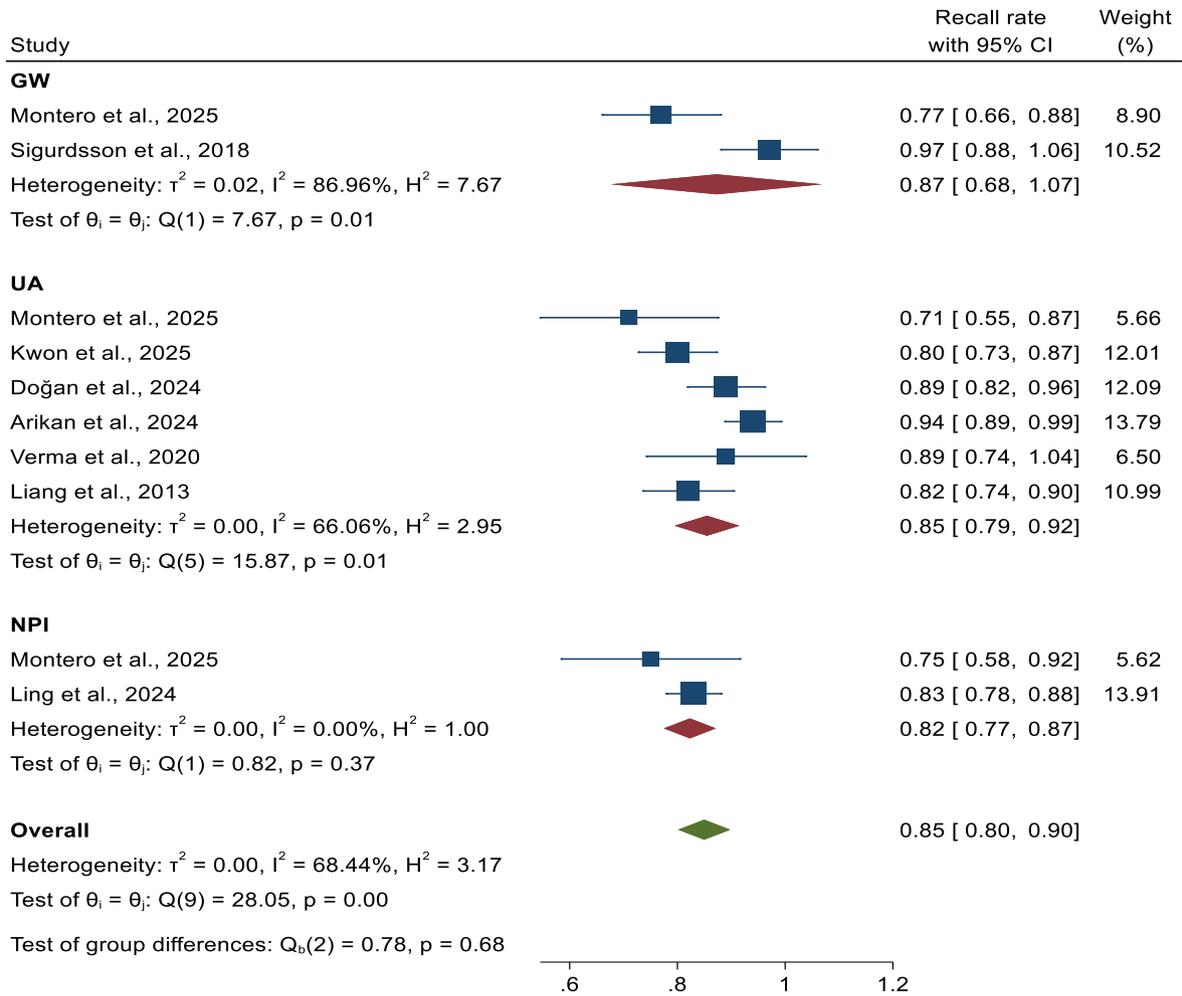


Fig. 2. Forest plot for healing rate using different root canal disinfection methods.



Random-effects REML model

Figure 3. Forest plot for the recall rate using different root canal disinfection methods.

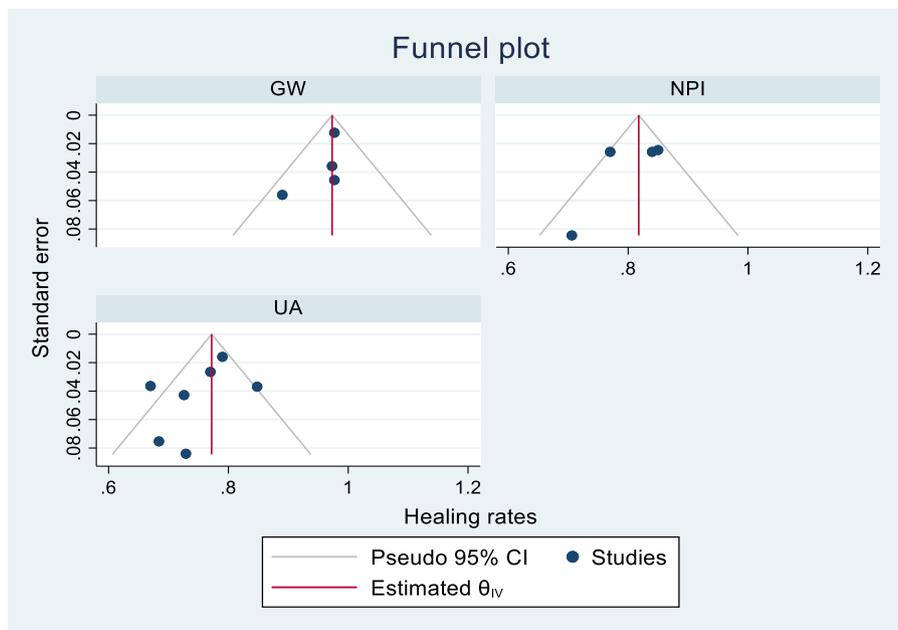


Figure 4. Funnel Plot Analysis and Publication Bias Assessment.

#### 4. Discussion

This is the first meta-analysis comparing different root canal disinfection methods for the healing of apical periodontitis. In the present study, prospective RCT and cohort articles were selected, which included all AP studies after primary root canal treatment and retreatment, using three novel approaches: GW, UA, and NPI systems. Meta-analysis showed that healing of apical periodontitis was significantly higher in patients treated with the GW system compared with the UA and NPI methods. These findings were consistent with previous studies.<sup>[27-29]</sup> Filling the gaps in the literature, this study compared the clinical outcomes of contemporary root canal disinfection techniques in a larger sample with a median follow-up period of 12 months. Based on the present meta-analysis, the GW system showed the highest clinical improvement rate and demonstrated high efficacy in completely removing necrotic tissues and accelerating the healing process. Both GW and UA, as well as NPI, technologies utilize negative pressure at the apical level during the activation of irrigants. However, the current GW protocol involves a final irrigant in EDTA, whereas UA and NPI use a final rinse with NaOCl. Therefore, there is a limitation to the current GW protocol, and it is necessary to perform a final rinse with NaOCl in new GW protocols, as it provides better penetration into the dentinal tubules after removing the smear layer. A systematic review also showed that UA was superior for removing pulp tissue and debris, emphasizing the need for further research on its antimicrobial effects in apical periodontitis.<sup>[31]</sup> Therefore, the use of advanced irrigation techniques was chosen to standardize the instrumentation protocol and focus on evaluating the disinfection process. The GW system recommends the use of ISO 20/06 apical instrumentation to minimize instrumentation and preserve dentin. The present study did not follow this guideline due to the lack of supporting clinical evidence. Current literature suggests that apical sizes above 30 have a higher success rate (80.9%) compared to sizes below 30 (52.9%).<sup>[32]</sup>

#### 5. Conclusion

Based on the present meta-analysis, the GW system was found to be more effective than NPI and UA in improving apical periodontitis. However, all three protocols had high healing rates for endodontic disinfection. Further studies are needed to evaluate all confounding factors to confirm the current evidence. Also, more clinical trial studies are needed to examine and compare all three methods.

#### Conflict of Interest

The authors declared that there is no conflict of interest.

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