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DOI: 10.46903/gjms/23.1.1683

REVIEW ARTICLE

DETERMINING THE DIFFERENCES BETWEEN THE RATES OF SMOKING CESSATION USING E-CIGARETTES VS NICOTINE-REPLACEMENT THERAPY: A META-ANALYSIS AND SYSTEMATIC REVIEW OF RANDOMIZED CONTROLLED TRIALS

Iqra Ayesha Jawad[1], Aqsa Ayesha Masood[2], Muhammad Zeeshan Ali[2], Jawad Safdar[1]

Departments of APS, [1]College of Rehabilitation Sciences Faisalabad, [2]Children's Hospital, Lahore, Pakistan

ABSTRACT

Both e-cigarettes (electronic cigarettes) and nicotine-replacement therapy (NRT) are employed to help people quit smoking, though some healthcare professionals still approach e-cigarettes with caution. This review aimed to compare their effectiveness for short- and long-term cessation. Studies were searched in MEDLINE and The Cochrane Central Register of Controlled Trials (CENTRAL), focusing on randomized trials involving participants in the contemplation stage of quitting. The review assessed NRT and e-cigarettes, primarily evaluating dichotomous quitting rates one year after cessation and data was rated using GRADE. The review included six RCTs with 1883 participants; 943 control group and 940 intervention group with a median age of 41.5 years. We observed that e-cigarettes increased the rate of 7-day point abstinence at 6 months or longer to 28% compared to 20% for NRT, with an RR of 1.43 and a 95% CI ranging from 1.19 to 1.72, though with low certainty. E-cigarettes did not offer significant improvements in 7-day point abstinence rates at 3 to 6 months, with rates of 22% compared to 21% for NRT and an RR of 1.01, along with a 95% CI between 0.70 and 1.44, showing low certainty. Similarly, there were no notable benefits at less than 3 months, where the abstinence rate was 38% compared to 29%, with an RR of 1.19 and a 95% CI from 0.92 to 1.54, also with low certainty. E-cigarettes did, however, show an increase in the persistent smoking cessation rate at 6 months or more, with an RR of 1.67 and a 95% CI ranging from 1.24 to 2.25, though this was determined with very low certainty. No significant benefits were observed for persistent smoking cessation at less than 3 months, where the RR was 1.37 with a 95% CI between 1.19 and 1.58, or at 3 to 6 months, where the RR was 1.12 with a 95% CI interval from 0.84 to 1.5, also with very low certainty. E-cigarettes were superior to NRT for both primary and secondary outcomes at ≥6 months, but no evidence supported their superiority at <6 months. Future research should investigate the both long-term safety and efficacy of e-cigarettes versus NRT across diverse populations and conditions.

KEY WORDS: Nicotine; Replacement; Therapy; Electronic; Cigarette; Smoking; cessation.

Cite as: Jawad IA, Masood AA, Ali MZ, Safdar J. Determining the differences between the rates of smoking cessation using e-cigarettes vs NRT: a meta-analysis and systematic review of randomized controlled trials [review article]. Gomal J Med Sci 2025 Jan-Mar;23(1):82-90. https://doi.org/1046903/gjms/23.1.1683

INTRODUCTION

Approximately 1.3 billion people globally use tobacco, leading to over 8 million deaths annually.[1] Quitting smoking at any age benefits health, with cessation before age 40 reducing the risk of smoking-related death by 90%.[2] Nicotine drives addiction, but cigarette smoke contains over 4,000 chemicals, including 69 known carcinogens like acetaldehyde, benzene, and formaldehyde.[3] The tar in cigarette smoke can obstruct bronchioles, impair oxygen exchange, and increase the risk of respiratory infections and cancers. Smoking also elevates carbon monoxide levels, reducing oxygenation and affecting oral health, potentially leading to oral cancers. [4-6]

Several smoking cessation methods are available to suit different needs. Recently, e-cigarettes have emerged as a potential aid for quitting.[7] These de-

Corresponding Author:

Dr. Jawad Safdar
Director
Department of APS
College of Rehabilitation Sciences
Faisalabad, Pakistan
E-mail: jawad.safdar87@gmail.com

Date Submitted: 31-07-2024
Date Revised: 09-03-2025
Date Accepted: 12-03-2025

vices use a battery to vaporize a liquid, or "e-juice," which contains nicotine, propylene glycol, flavorings, and other chemicals. E-liquids are central to vaping, providing an alternative to traditional smoking through the inhalation of vaporized nicotine and flavors.[8, 9] E-cigarettes offer various nicotine levels, enabling users to control their nicotine consumption and alleviate cravings and withdrawal symptoms, like irritability and low mood.[7] Vaping is often seen as effective because it replicates the hand-to-mouth habit of smoking. Additionally, vaping presents fewer health risks compared to traditional cigarettes, as it does not produce tar or carbon monoxide, two of the most harmful substances found in cigarette smoke.[7,10]

NRT helps reduce the urge to smoke and alleviates nicotine withdrawal symptoms, helping the shift from smoking to thorough abstinence. NRT is available in various forms, including gum, nasal spray, transdermal patches, inhalers, and sublingual tablets.[11] Nicotine, the key addictive component in tobacco, reinforces smoking behaviors. NRT helps manage tobacco cravings and withdrawal symptoms by providing controlled nicotine doses.[7, 11] In a review by Hartmann-Boyce[12] NRT improves the chances of quitting smoking by 50% to 60% across different contexts, with its effectiveness remaining steady regardless of additional support, though intensive support can further enhance quit rates. Thus, NRT is a highly effective smoking cessation method, often combined with behavioral support to address adherence issues. Conversely, e-cigarettes are popular among smokers for their variety of flavors and attractive designs, leading to higher satisfaction levels.[13]

The effectiveness of e-cigarettes against NRT varies, with some studies indicating that e-cigarettes result in 1.6–3.2 times higher smoking cessation rates compared to NRT.[14]; however, the RCTs present conflicting evidence. A systematic review by Li [13] found e-cigarettes better than NRT for long-term cessation, while Pound [15] reported no significant differences in cessation rates, harm, or smoking reduction between the two methods. To address these inconsistencies, we conducted a thorough review to compare the effectiveness of e-cigarettes and NRT for smoking cessation.

MATERIAL AND METHODS

We conducted a systematic review of randomized controlled trials (RCTs) following the guidelines set by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[16] An extensive search was performed in Medline and the Cochrane Library using electronic search methods. Our search utilized terms related to both the intervention, such as electronic cigarettes, vaping, and e-cigs, electronic nicotine delivery systems, and the control, including nicotine patches, and NRT, nicotine gum. We focused on studies involving human participants and prioritized publications in English. The complete search strategy and specific terms are outlined in the Supplementary file. Titles and abstracts of all identified studies were independently reviewed by three authors (AAM, IAJ, and MZA) according to predefined selection criteria. Full-text articles that met these criteria were then retrieved and further assessed by the same reviewers.

Data from the trials were extracted independently by three reviewers (AAM, IAJ, and MZA) using a data extraction form provided by Covidence [17]. Following extraction, both reviewers cross-checked the data for accuracy and compliance with inclusion criteria. The extracted information included study characteristics such as design, number of centers, sample size, trial registration numbers, inclusion/exclusion criteria, and patient demographics. It also covered details on the study duration, reported outcomes, and timing of outcome assessments. Six studies were included in the meta-analysis, all of which had complete outcome data. The trial authors were contacted for any additional data or to address any missing data issues.

Potential sources of bias in the RCTs were evaluated using the Cochrane [18] Collaboration's risk of bias tool, which examines seven areas: blinding of outcome assessment, allocation concealment, incomplete outcome data, random sequence generation, selective reporting, blinding of participants and personnel, and other sources of bias. Each study was categorized as having a low, unclear, or high risk of bias in these domains.[18, 19]

To assess the certainty of the evidence, we employed the GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) system. [20] This system rates the certainty of evidence as very low, low, moderate, or high based on several factors that could affect certainty: publication bias, indirectness, imprecision, risk of bias, and inconsistency. The main results were summarized in a table "Summary of Findings" generated using GRADEPro software, which included footnotes explaining the rationale for any downgrades in evidence certainty.

The studies included in the systematic review were selected based on the following criteria: i) inclusion of adult human participants, ii) only randomized controlled trials (RCTs) were considered, iii) publications must be in English, iv) availability of the full research article for review, v) completion of the study with reported results, vi) adherence to pre-specified participant eligibility criteria (see eligibility criteria), vii) comparison between NRT and e-cigarettes, with outcomes including continuous abstinence rates at 0–3 months, 3–6 months, and 6–12 months, as well as 7-day point prevalence of abstinence, and viii) exclusion of non-randomized studies, observational studies, abstracts, and other non-peer-reviewed types of research.[13,21,22]

The following criteria were used to select and include

studies in the systematic review: i) Trials must involve adult smokers aged 15-65 years, including those who are current smokers with a history of smoking at least 100 cigarettes in their lifetime or those who have smoked at least 10 cigarettes in the past year [23], ii) Participants should not be using NRT or e-cigarettes at the time of recruitment and should not have a strong preference for or against these methods for their quit attempt; iii) Participants must be in the contemplation stage of smoking cessation; and iv) Participants must provide informed consent. The following criteria were used to exclude studies from the systematic review: i) Individuals already attempting other smoking cessation methods or participating in related programs, ii) Participants outside the specified age range, iii) Individuals with co-morbidities such as diabetes, severe allergies, respiratory conditions, psychiatric disorders, substance dependence other than nicotine, high blood pressure, or cardiovascular disease, iv) Pregnant or breastfeeding women, v) Those currently using smoking cessation therapies, including e-cigarettes or NRT, and vi) Individuals who did not provide informed consent or were unwilling to participate in follow-up.[13]

The intervention involves using e-cigarettes for 8-12 weeks. Participants receive battery-powered e-cigarettes with disposable cartridges resembling tobacco filters, which are filled with a solution of propylene glycol, vegetable glycerin, and either nicotine or flavoring. E-cigarettes are provided initially and during regular follow-up visits. Participants are monitored for up to 12 months, with exhaled Carbon Monoxide (eCO) levels being tracked. The comparison group uses nicotine replacement therapy (NRT) in any form. At the baseline visit, participants choose their preferred NRT product or combination and are instructed to obtain additional supplies from their local pharmacy every 2 weeks for up to 12 weeks. They are advised to use NRT daily and to attempt to quit smoking. Follow-up visits occur within 12 months, during which exhaled Carbon Monoxide (eCO) levels are measured.

Smoking cessation is measured by assessing continuous abstinence 12 months after starting the intervention, using exhaled Carbon Monoxide (eCO) levels. According to NICE guidelines, smoking cessation is confirmed if eCO levels are below 10 ppm at 4 weeks post-quit date.[24] The secondary outcome is abstinence on the 7th day following the intervention. Smoking cessation is determined by measuring end-expired CO levels with a CO monitor, using a cutoff of <8 parts per million to validate self-reported abstinence.[24]

We used the Mantel-Haenszel method and pooled data with a random-effects model, presenting dichotomous outcomes as risk ratios with 95% confidence intervals. Heterogeneity was evaluated through visual inspection, the Chi^2 test (with $P < 0.05$ as significant), and I^2 statistics, interpreted as follows: i) minimal (0% to 40%), ii) moderate (30% to 60%), iii) substantial (50% to 90%), and iv) considerable (75% to 100%). We also considered clinical and methodological heterogeneity to form an overall view. Subgroup analysis was performed for different time intervals, and data analysis was conducted using Review Manager Software (version 5.4).[13, 25, 26]

RESULTS

The PRISMA flow diagram illustrates the process of identifying relevant randomized controlled trials, as shown in Figure 1. We retrieved 513 articles from databases and reference lists. After removing 69 duplicates and excluding 418 articles that did not meet the selection criteria, we assessed the full texts of the remaining 25 articles. From these, we included 6 RCTs in the final analysis. The characteristics of all six studies are presented in Table 1. The eligible studies contain a total of 1883 participants including 943 in the control group and 940 in the intervention group with a median age of 41.5 years. All the included studies were published from 1946-2022, two from the United Kingdom[27,28] and one from Australia[29] used nicotine replacement therapy, one from the USA[30] and New Zeeland [31] used nicotine patches, one from Korea [32] used nicotine gums. The different studies compared NRT therapy vs E-cig for smoking cessation in smokers for different time periods i.e., two studies <6 months[30, 32], three studies for 6 months[27,29,31] and one study for 12 months.[28]

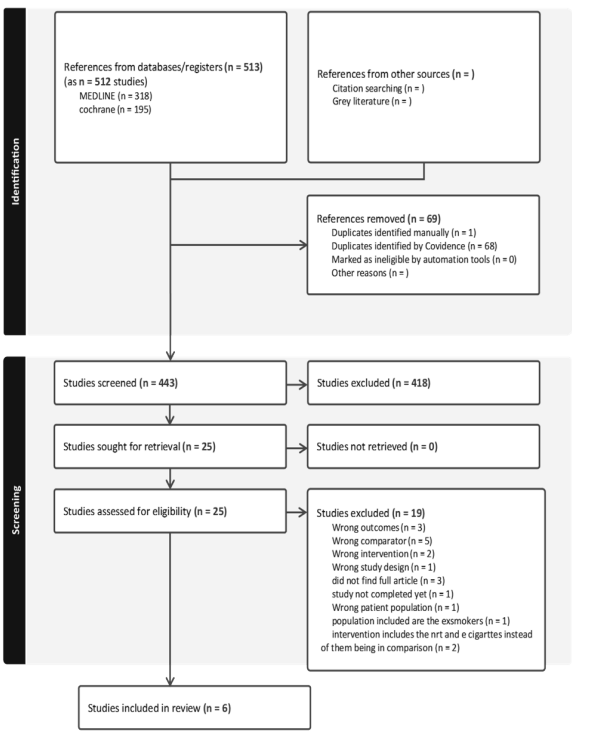

Figure 1: PRISMA flow diagram for identification of randomized control trials

Table 1: Characteristics of the included randomized control trials (RCTs)

Author Year	Follow Up Period (Months)	Country	Products used INV / CNT groups	Participants					
				Total (n)	Intervention group (n)	Control group (n)	Median Age (years)	Pri and Sec outcomes in INV and CNT group at One year and 7 days (n)	Lost to follow-up days (n)
Myers 2022	6	UK	E-cigarettes / NRT	135	68	67	41	5/34, 7/29 13/67, 2/67	NA
Bonevski 2021	6	AUS	E-cigarettes / NRT	100	50	50	40.9	9/25,10/25 7/25,9/25	50
Lee 2019	3	KOR	E-cigarettes / Nicotine gums	150	75	75	42.3	16/75,21/75 17/75,22/75	18
Hajek 2019	12	UK	E-cigarettes / NRT	884	438	446	41	79/438,44/446 61/289,46/295	188
Bullen 2013	6	NZ	E-cigarettes / Nicotine patches	584	289	295	42	21/289, 17/295 61/289, 46/295	128
Lee 2018	4.5	USA	E-cigarettes / Nicotine patches	30	20	10	53.7	5/20 1/10 NA	6

Figure 2 represents the risk of bias across all the studies reviewed. There were three studies free from bias across all domains. Two studies had a high risk of bias in at least one area, specifically due to missing outcome data, while one had a high risk of bias related to the randomization process, and another raised concerns about selection bias in reported data. All RCTs included provided adequate descriptions of their randomization processes, including allocation concealment and sequence generation, except for Bullen 2014, which offered only brief statements like "patients were randomized into two groups." Participant blinding was not feasible in any of the studies, but this lack of blinding did not impact the outcome assessments. No imbalances in baseline characteristics were found in the included trials, although Bullen 2013 and Bovenski exhibited significant concerns regarding bias from confounding factors related to missing outcome data (Figure 2).

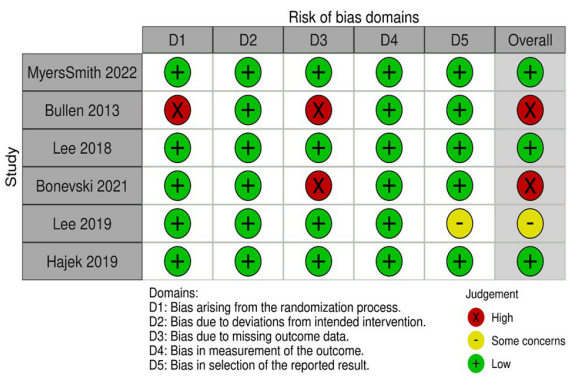

Figure 2: Risk of bias in different domains across all the included randomized controlled trials

Both e-cigarettes and nicotine-replacement therapy (NRT) appear to enhance smoking cessation rates at different follow-up intervals: 6 months or more (13.8% vs 8.2%), 3 to 6 months (21% vs 12.9%), and 0 to 3 months (35.3% vs 25.9%), as detailed in Table 2. The meta-analysis indicated that e-cigarettes were linked to a higher rate of continuous smoking cessation compared to NRT at 6 months or more, with a relative risk of 1.67 and a 95% confidence interval from 1.21 to 2.28, which translates to 55 more quitters per 1,000 people, though this result had very low certainty. Conversely, e-cigarettes did not demonstrate a significant benefit over NRT for continuous abstinence at less than 3 months, with a relative risk of 1.27 and a 95% confidence interval between 0.97 and 1.66, equating to 70 more quitters per 1,000, or at 3 to 6 months, with a relative risk of 1.31 and a 95% confidence interval from 0.75 to 2.3, corresponding to 72 more quitters per 1,000, both with very low certainty. Statistical heterogeneity was 57% for the 0 to 3 months follow-up, 59% for 3 to 6 months, and 6% for the 6 to 12 months follow-up periods, as shown in Figure 3.

In the 0–3 months subgroup, the point estimates from the two studies diverge, and the I^2 statistic is 55%. Despite this, we have not downgraded the evidence due to heterogeneity, as it can be attributed to differences in control groups and additional comparison groups across studies. Among the studies on either side of the forest plot, Lee 2018 has the smallest sample size, while Bullen 2013 includes three arms, of which only two were considered in our analysis (Figure 3).

For the 3–6 months subgroup, a visual examination of the forest plot reveals that the point estimates from the two studies lie on opposite sides of the null effect. The point estimates of nearly all studies overlap, and the statistical test for heterogeneity yields a P-value of 0.01, indicating statistical significance, with an

Table 2: Summary of the findings table for continuous smoking cessation (up to 12 months)

Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	E cigarettes	NRT	Relative (95% CI)	Absolute (95% CI)	
6	randomized trials	+	–	–	++	none	326/924 (35.3%)	239/922 (25.9%)	RR 1.27 (0.97 to 1.66)	70 more per 1,000 (from 8 fewer to 171 more)	⊕◯◯◯ Very low
6	randomized trials	+	+	–	++	none	101/477 (21.2%)	61/472 (12.9%)	RR 1.56 (1.16 to 2.10)	72 more per 1,000 (from 21 more to 142 more)	⊕◯◯◯ Very low
2	randomized trials	+	–	–	++	none	100/727 (13.8%)	61/741 (8.2%)	RR 1.67 (1.21 to 2.28)	55 more per 1,000 (from 17 more to 105 more)	⊕◯◯◯ Very low

Note: ++ = Very serious, + = serious, – = not serious

Table 3: Summary of findings table for 7th-day smoking abstinence

Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	E cigarettes	NRT	Relative (95% CI)	Absolute (95% CI)	
4	randomized trials	+	–	–	++	none	318/844 (37.7%)	244/837 (29.2%)	RR 1.19 (0.92-1.54)	55 more per 1000 (-23-157)	◯⊕◯◯ low
3	randomized trials	–	–	–	++	none	86/389 (22.1%)	81/395 (20.5%)	RR 1.01 (0.7-1.44)	2 more per 1000 (-62-90)	◯⊕◯◯ low
2	randomized trials	+	–	–	++	none	207/735 (28.2%)	144/733 (19.6%)	RR 1.43 (1.19-1.72)	84 more per 1000 (37-141)	◯⊕ ◯◯ low

Note: ++ = Very serious, + = serious, – = not serious

I^2 of 59%, reflecting moderate heterogeneity. No substantial differences in population, intervention, control, or outcome could be identified to explain this variability, leading us to downgrade the evidence for heterogeneity (Figure 3).

In the 6-12 months subgroup, the forest plot shows consistent point estimates with overlapping confidence intervals and minimal heterogeneity (I^2 = 6%). However, all subgroups face serious risks of bias and imprecision, resulting in very low certainty of evidence for the primary outcome.

The risk ratios for smoking cessation with e-cigarettes compared to nicotine-replacement therapy (NRT) for 7-day point abstinence are 1.19 with a 95% confidence interval of 0.92 to 1.54 at 0 to 3 months, 1.01 with a 95% confidence interval of 0.70 to 1.44 at 3 to 6 months, and 1.43 with a 95% confidence interval of 1.19 to 1.72 at 6 to 12 months, as shown in Table 3. The meta-analysis suggests that e-cigarettes are linked to a higher 7-day point abstinence rate compared to NRT at 6 months or longer, with 28% versus 20% and a relative risk of 1.43, a 95% confidence interval from 1.19 to 1.72, and 84 more successful quitters per 1,000, though this result has low certainty. In contrast, e-cigarettes did not show a significant advantage over NRT for 7-day point abstinence at 3 to 6 months, with rates of 22% versus 21%, a relative risk of 1.01, and a 95% confidence interval from 0.70 to 1.44, resulting in 2 more quitters per 1,000, or at less than 3 months, with rates of 38% versus 29%, a relative risk of 1.19, and a 95% confidence interval from 0.92 to 1.54, which translates to 55 more quitters per 1,000, both with low certainty. These results indicate that e-cigarettes might be more effective for smoking cessation when used for more than 6 months. Statistical heterogeneity was 65% for 0 to 3 months, 31% for 3 to 6 months, and 0% for 6 to 12 months, as depicted in Figure 4 and Table 3.

In the 0–3 months subgroup, the point estimates from two studies support the efficacy of e-cigarettes, while the other two favor NRT. Despite a significant heterogeneity indicated by a P-value of 0.01 and an I^2 of 65%, we did not downgrade the evidence, as this heterogeneity appears to stem from differences in control groups and additional comparison groups

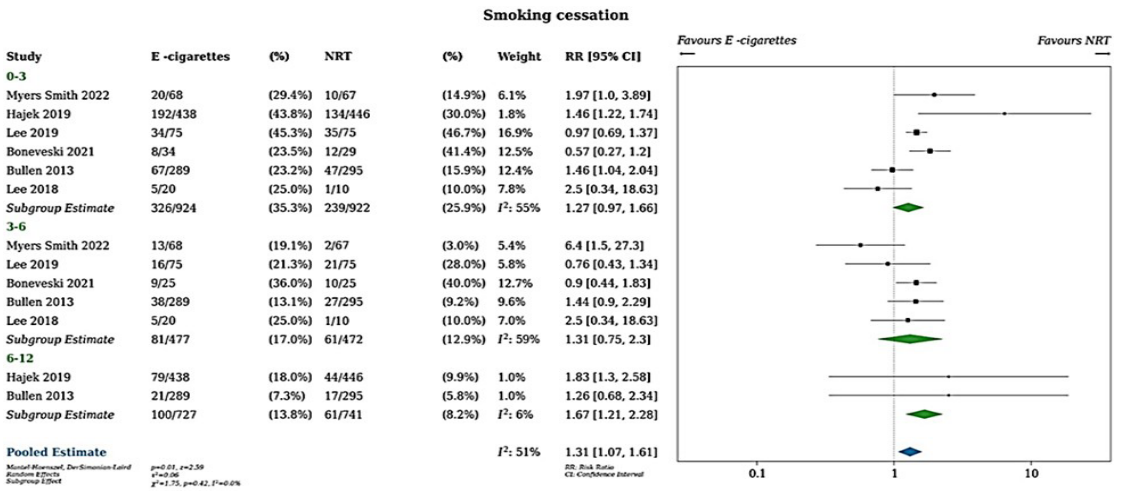

Figure 3: Subgroup analysis of smoking cessation rate in study participants administered with NRT vs e-cigarette

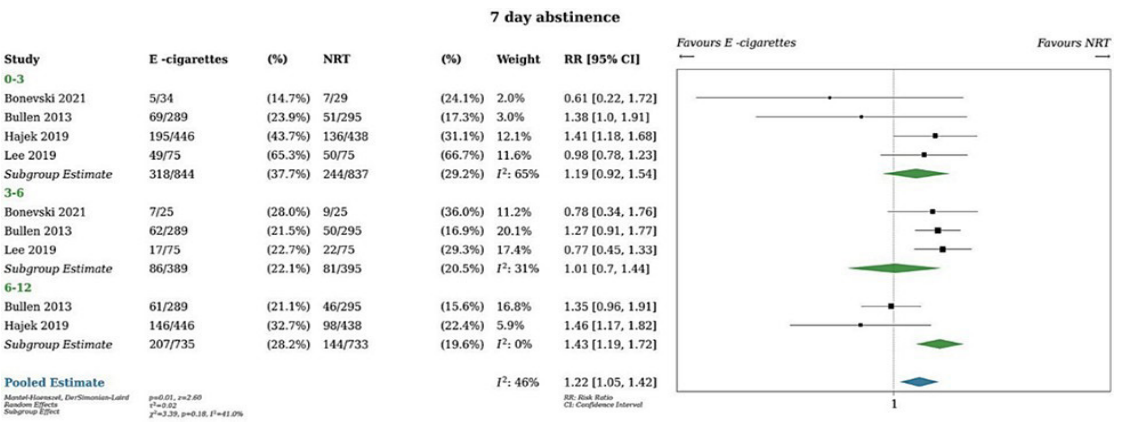

Figure 4: Subgroup analysis at 7-day abstinence rate in study participants administered with NRT vs e-cigarette

within the studies (Figure 4).

For the 3–6 months subgroup, all studies present point estimates on the same side, and there is substantial overlap among these estimates. The heterogeneity test also shows a significant P-value of 0.01 and a lower I^2 of 31%, indicating minimal heterogeneity among studies (Figure 4).

In the 6–12 months subgroup, the forest plot shows that the point estimates from both studies are aligned and their confidence intervals overlap. The I^2 value is 0%, demonstrating no apparent heterogeneity (Figure 4).

DISCUSSION

The meta-analysis included a total of 1,883 participants, with 943 in the control group and 940 in the intervention group. Both e-cigarettes and nicotine replacement therapy (NRT) were found to enhance smoking cessation rates at various time points: ≥6 months (13.8% vs 8.2%), 3–6 months (21% vs 12.9%), and 0–3 months (35.3% vs 25.9%). This also indicates that e-cigarettes are linked to a higher rate of continuous abstinence and 7-day point abstinence at follow-up periods of 6 months or more when compared to NRT, though this is with a low level of certainty. However, the advantages of e-cigarettes in achieving continuous abstinence were not significant for follow-up periods of less than 6 months, nor were they for the 7-day point abstinence rate. This may suggest that e-cigarettes are more effective than NRT for long-term smoking cessation.

Our findings align with those of a study from Grabovac[33], a systematic review of three RCTs[28,30,31] involving 1,498 participants, which concluded that e-cigarettes were more effective than NRT for smoking cessation (RR=1.69; 95% CI: 1.25–2.27). Another review by Hartmann-Boyce [34] which included four RCTs with 1,924 participants, also found higher quit rates with e-cigarettes compared to NRT (RR=1.53; 95% CI: 1.21–1.93). However, their study did not address subgroup analysis based on follow-up duration, a factor we examined, revealing potential variations in continuous abstinence rates over different periods.

Li [13] performed a systematic review including 1,748 participants from five RCTs, and their analysis suggested that e-cigarettes, compared to NRT, improved the ≥6 months continuous abstinence rate (RR=1.67; 95% CI: 1.21–2.28; low certainty) and the 7-day point abstinence rate at ≥6 months follow-up (RR=1.43; 95% CI: 1.19–1.72; low certainty). Additionally, Li[13] included two more RCTs[29,32], focusing on significant patient outcomes such as continuous abstinence rate and 7-day point abstinence rate. The continuous abstinence rate has the advantage of being more consistent over time and across studies compared to point prevalence rates. In our meta-analysis, we incorporated one additional RCT[27] and found the risk ratio for smoking cessation in the e-cigarette group versus the NRT group to be 1.19 (95% CI: 0.92–1.54) at 0–3 months, 1.01 (95% CI: 0.7–1.44) at 3–6 months, and 1.43 (95% CI: 1.19–1.72) at 6–12 months for 7th-day point abstinence. Our findings are consistent with the conclusions of the previously discussed systematic reviews.

The strengths of our study include limiting the inclusion to only RCTs, applying the GRADE system to determine absolute effects for each outcome, and assessing the certainty of evidence. Additionally, we conducted subgroup analyses based on various follow-up durations to investigate the impact of short-term, mid-term, and long-term follow-up on smoking cessation outcomes between e-cigarettes and NRT. We concentrated on significant patient outcomes, such as continuous abstinence rate and 7-day point abstinence rate, both of which can be biochemically validated.[28,30,31]

However, our review has some limitations. There is potential heterogeneity due to the varying doses and courses of e-cigarettes and NRT across different studies. Another source of heterogeneity may arise from the diversity of NRT regimens, such as nicotine gum, patches, or inhalators. Additionally, no studies included pregnant women or considered potential harm to fetal organs from e-cigarettes, making our results inapplicable to this particular or special population.[13] Missing data from the included studies could also introduce bias into our review.

CONCLUSIONS

Our study indicates that e-cigarettes may offer better outcomes for smoking cessation in the long term compared to NRT, but do not demonstrate a significant advantage in the short term. Specifically, while e-cigarettes excel in maintaining continuous abstinence and achieving 7-day point abstinence after 6 months, they do not outperform NRT in these outcomes for periods shorter than 6 months. This suggests potential adverse effects associated with short-term e-cigarette use when combined with ongoing cigarette use. Further research should focus on exploring the long-term safety and efficacy of e-cigarettes compared to NRT, particularly in different populations and under varying usage conditions. Additionally, one should investigate the potential adverse effects of short-term e-cigarette use and its impact on overall smoking cessation strategies.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
GRANT SUPPORT AND FINANCIAL DISCLOSURE
None declared.

AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

Conception or Design:	IAJ, AAM
Acquisition, Analysis or Interpretation of Data:	IAJ, AAM, MZA, JS
Manuscript Writing & Approval:	IAJ, AAM, MZA, JS

All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.