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The diagnostic accuracy of currently available laboratory tests compared to PCR test for COVID-19: a systematic review and meta-analysis

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ABSTRACT: Coronavirus disease (COVID-19) is caused by SARS-COV-2 and represents the causative agent of a potentially fatal and pandemic viral disease that is of great global public health concern and high transmutation rate and mechanisms. A comprehensive systematic search was performed on PubMed, Scopus, Web of Science, and Google Scholar, to find articles published until March 30, 2020. All relevant articles that reported clinical characteristics and laboratory result information of hospitalized COVID-19 patients were included in the analysis. Based on our analysis, however, articles not used RT-PCR and CT as were excluded all of the randomized controlled trial (RCT) were homogeneous (I^2=94.58% and p≤0.001) statistical tests showed no publication bias/small study effect. Accordingly, the result of meta-analysis illustrated that RT-PCR increased cases of laboratory confirmation by more than 99% (95% CI: -1.3.0; 4.74) than other laboratory tests. As a result, this finding, is recommended to pilot and scale-up well and accurate laboratory techniques is used in developing countries, and is essential to prevent and control the pandemic diseases with spread in the world. However, it is recommended to further investigate the adverse effects of Real-time reverse transcriptase polymerase chain reaction (RT-PCR) before fully implementing the confirmation.

KEYWORDS: COVID-19; Comprehensive systematic review; Meta-analysis; RT-PCR

INTRODUCTION

In December 2019, reports emerged from China of a new flu-like virus affecting many people in the city of Wuhan [1] and caused by 2019 novel coronavirus (2019-nCoV) [2]. It is a novel beta-coronavirus that is currently named 2019 novel coronavirus, which was identified by deep sequencing analysis from lower respiratory tract samples [3-5].

As recently identified numerous of coronavirus in beta subfamily, these kind of virus that is similar with more than 85% homology with the bat species of severe acute respiratory syndrome (SARS)-like coronavirus which is called (bat SLCoVZC45), part of the similar class as the SARS-CoV found in 2003 and the Middle East respiratory syndrome virus (MERS-CoV) found in 2012 [6-8]. Over all, genetic analysis of the strain has been demonstrated that the virus is a different branch from SARS-CoV and MERS-CoV [9-11]. Human-to-human transmission of SARS-CoV-2 occurs mainly between family members, including relatives and friends who intimately contacted with patients or incubation carriers [12-14].

The total number of COVID-19 suspected cases and confirmed patients increased dramatically due the reason of millions of people traveling during the Spring Festival period. The severity of COVID-19 had been underestimated and ignored by the majority of our community until the National Health Commission classified it as a B infectious disease officially and took action to fight against this disease on 20 January, 2020. Forever subsequently, the epidemic prevention and control mechanism's was comprehensively upgraded and marked the real beginning of universal concern and it is a big problem for the higher officials, indicating the widespread impacts and the way it transmit [15]. Real-time reverse transcriptase polymerase chain reaction (rRTPCR), it is essential to detect SARS-CoV-2 using the published identical sequences and conserved regions of the virus. The cycle threshold (Ct) value of the virus is measured by rRT-PCR is converted into RNA copy number of SARS-CoV-2 [16].

Previous studies have shown that survivors of acute infectious diseases, such as SARS, can lead to anxiety, depression, stress, and posttraumatic stress disorder. However, there have been few studies on the physical and psychological effects of outbreaks of serious infectious diseases on the medical staff, particularly when associated with increased workload and stress associated with the risk of infection [17].

Today, the world faces many complex problems, such as emerging infections, that a single discipline, institution, or country cannot respond to alone. The human pulmonary system is vulnerable to infections due to contact-based inoculation of infectious material in droplets through the eyes, nose, or mouth, and airborne transmission is effective as seen, e.g. in the plethora of viral respiratory diseases affecting individuals of all age groups from SARS to COVID-19: A previously unknown SARS- related coronavirus [18].

Currently, information on the COVID-19 diagnosis mechanisms of this pandemic viral disease is rare [19-22]. Moreover, knowing the underlying diseases in COVID-19 infected patients is important for to protect the spread of the disease and increases the control and prevention mechanism in the world. In the current systematic review and meta-analysis was conducted on the diagnostic accuracy of formerly accessible laboratory tests for COVID-19 compared to temperature measurement as a reference examination amongst people presenting with suspected COVID-19 with the research question of: What is the diagnostic accuracy of currently available laboratory tests for COVID-19 compared to temperature measurement as a reference test amongst people presenting with suspected COVID-19?

The objective of this study was the comprehensive type of review that examined the accuracy of current diagnostic tools of amongst COVID-19 suspected people as compared to PCR by generates pooled evidence.

MATERIALS AND METHODS

All COVID-19 patients that confirmed by laboratory test of RT-PCR as a continuous variable was considered as the outcome measure. In the countries that addressed this disease, the high burden of pandemic viral disease of COVID-19, current viral disease outbreak diagnosis accuracy methods, and it's clinical signs and symptoms related to the patient that suspected to COVID-19. The clinical parameters tablets were composed of standard 11 COVID-19 patients (Table 1).

Table 1. Inclusion and exclusion criteria for a systematic review of diagnostic accuracy of currently available laboratory tests compared to PCR for COVID-19

PIRD	Inclusion criteria	Exclusion criteria
Population	Patients with COVID-19	Other patients
Index test	CT	Other than CT
Reference test	RT-PCR	Other than RT-PCR
Diagnosis of interest	Disease of COVID-19	Literatures not reporting
Other criteria's	Case, retrospective studies ,published in English	Studies not accessible in free full text

Study selection

In this systematic review, case and retrospective studies whose free full text was freely available and published in English language were included. However, articles not used RT-PCR and CT as were excluded.

Search strategy

Major databases i.e., PubMed, Google, and Google Scholar, were used to identify potential and relevant articles. Furthermore, the references of the published articles were checked to identify additional literatures. Search term includes: 2019 novel coronavirus disease; COVID-19; COVID-19 pandemic; SARS-CoV-2 infection; COVID-19 virus disease; 2019 novel coronavirus infection; 2019-nCoV infection; coronavirus disease 2019; coronavirus disease-19; 2019-nCoV disease; COVID-19 virus infection for the above databases were developed following exhaustive searching of the synonyms of each term specific to PIRD (Table 2).

Up to searching through the above search strategies, a total of 516 and 25 literatures were obtained from PubMed and Cochrane databases, respectively. Moreover, 36 papers were identified manually through checking the reference lists of relevant studies. Literatures (516 from PubMed, 25 Cochrane, and 36 reference checking) of the two databases were exported to endnote version 6 following preliminary screening through the title of articles. Following further screening through abstract and free full text, seven case and retrospective studies were included for analysis. Details of the literature searching results are described below using PRISMA checklist (Figure 1). There is graphically showed the additional results of searching from the two databases.

To find relevant studies, international databases including PubMed, Scopus, Web of Science, Google scholar, and Embase were searched for articles published until 16 February 2020. The following search terms were used (designed using English MeSH keywords and Emtree terms): [SARS-CoV-2 AND characteristics] OR [2019-nCoV AND Characteristics]" OR "COVID-19 AND Comorbidities] OR [new coronavirus AND Characteristics AND Comorbidities] OR [Wuhan Coronavirus AND Characteristics AND Comorbidities] OR [Coronavirus AND characteristics AND Comorbidities]. Additionally, extra searches were performed in the reference lists of the included studies to avoid missing papers. Moreover, Centers for Disease Control and Prevention (CDC) and World Health Organization (WHO) portals such as the national public health institute were evaluated. Due to the substantial number of articles in Chinese language, the abstracts were evaluated in these studies.

Table 2. Data base search terms built and strategy tools for a systematic review of diagnostic accuracy of currently available laboratory tests compared to PCR for COVID-19

Name of database	Search strategy
PubMed	((((((((((("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "2019 novel coronavirus disease"[All Fields]) AND ("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "covid19"[All Fields])) AND ("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "covid 19 pandemic"[All Fields])) AND (("severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR "severe acute respiratory syndrome coronavirus 2"[All Fields] OR "sars cov 2"[All Fields]) AND ("infections"[MeSH Terms] OR "infections"[All Fields] OR "infection"[All Fields]))) AND (("severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR "severe acute respiratory syndrome coronavirus 2"[All Fields] OR "covid 19 virus"[All Fields]) AND ("disease"[MeSH Terms] OR "disease"[All Fields]))) AND ("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "2019 novel coronavirus infection"[All Fields])) AND ("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "2019 ncov infection"[All Fields])) AND ("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "coronavirus disease 2019"[All Fields])) AND ("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "coronavirus disease 19"[All Fields])) AND ("COVID-19"[Supplementary Concept] OR "COVID-19"[All Fields] OR "2019 ncov disease"[All Fields])) AND (("severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR "severe acute respiratory syndrome coronavirus 2"[All Fields] OR "covid 19 virus"[All Fields]) AND ("infections"[MeSH Terms] OR "infections"[All Fields] OR "infection"[All Fields]))) AND ("loattrfree full text"[sb] AND "humans"[MeSH Terms] AND medline[sb] AND "adult"[MeSH Terms:noexp])
Cochrane	Cochrane Review matching 2019 novel coronavirus infection in Title Abstract Keyword OR *coronavirus disease 2019* in Title Abstract Keyword AND COVID-19 virus infection in Title Abstract Keyword AND 2019 novel coronavirus infection* in Title Abstract Keyword OR coronavirus disease 2019$ in Title Abstract Keyword - (Word variations have been searched

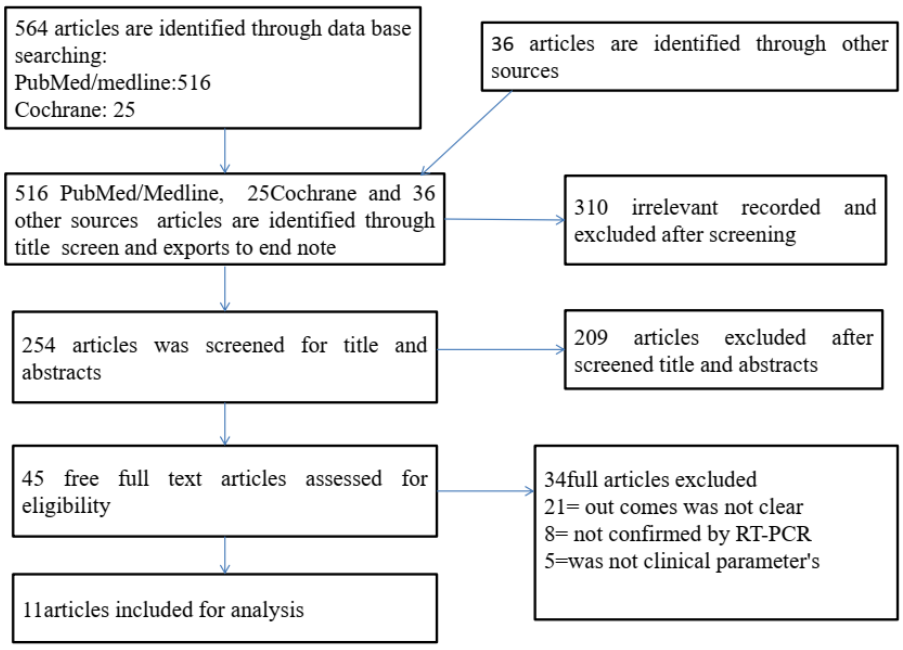


Figure 1. PRISMA checklist of literature searching results for a systematic review of diagnostic accuracy of currently available laboratory tests compared to PCR for COVID-19

Inclusion and exclusion criteria

Any relevant articles that reported clinical characteristics and epidemiological information on infected patients were included in the analysis. All articles with any design (case and retrospective studies) were included. Articles were excluded if appropriate information was not reported.

Quality appraisal and data extraction

Two authors (M.B. and N.B) screened and evaluated the literature independently. The following features were extracted for pooled estimation: name of the first authors and age, sex, and Laboratory types and results condition of the patients. Hence heterogeneity was expected, data on different independent variables were also extracted.

Data management and statistical analysis

Micro-soft Excel and STATA version 16 [23] were used for data extraction and analysis. Overall prevalence with 95% confidence interval was estimated via the inverse variance method. Heterogeneity was evaluated using chi-square and I^2. The random effect model was used in case of considerable heterogeneity, which was defined as I^2>79.29%. Sensitivity analysis was done according to the outlier data. Dersimonian Laird was used to evaluate publication biases. All statistical analyses were performed using STATA 16 metaprop command.

Because of these inconsistencies, P-values indicated in each study to check the statistical significance of the mean PCR mean difference were extracted; then the P-value was transformed to Z-value by referring the standard statistical table. Heterogeneity among the studies was checked using Forest plot, Galbraith plot, Cochrane's Q statistic ($p \leq 0.001$) and I^2. Cumulative meta-analysis was used to illustrate the patterns in the extent and statistical significance of the difference in mean RT-PCR between COVID-19 suspected cases. Sensitivity analysis was employed to check the influence of studies. Furthermore, the funnel plot, Eggers, and DerSimonian-Laird statistical tests were used to explore publication bias.

RESULTS

Features of the included studies

Of the total 11 potentially relevant full text articles, seven fulfilled the eligibility criteria. These were considered for meta-analysis. All of these literatures were case, retrospective studies and published in English, of which two were from Korea and Finland. Only the study from China used retrospective and clinical studies while the rest used the case study. Taking into account of the thresholds for converting the Cochrane Risk of Bias assessment results, the overall quality of studies was found in 'Good quality'.

Characteristics of included studies

In the initial search, 564 articles were found in different databases. All papers were screened by reading their abstracts and 289 of them were eliminated due to being duplicates found in different databases. After evaluating the free full texts, 288 studies were excluded due to presenting data that were irrelevant to our aim. 11 articles met the inclusion criteria, but some of the required information was not reported in all articles. Figure 1 shows the search details, and the characteristics of the included studies are provided in Table 2. Finally, the available data of 11 hospitalized patients with COVID-19 infection were used for the analysis.

Baseline characteristics of participants

Mean incubation period of the virus ranged from 3.9 to 25 days. The overall clinical parameter's follow-up was good. Furthermore, four studies reported the baseline health status of participants using in (Table 3).

Mean of COVID-19 suspected patient pooled results

According to the result of meta-analysis, COVID-19 confirmation of suspected cases is by RT-PCR. Using RT-PCR, laboratory confirmation method are higher significant than that of other tests and well-confirmed mechanism's for suspected cases (95% CI; -1.30, 4.74) (Table 5, and Figures 1-3 are described the forest plot, publication bias and Heterogeneity test) respectively. And the regression of the result and subgroup analysis of all the data are clearly described in (Tables 7 and 8), respectively. The output from the standard meta-analysis summary includes heterogeneity statistics, individual and overall effect sizes, and other information. The estimate of the overall effect size θ is reported at the bottom of the table and labeled as theta. It is computed as the weighted average of study-specific effect sizes (standardized mean differences in our example). For these data, the overall estimate is 1.719 with a 95% CI of [-1.30; 4.74]. The significance test of $H0$: $\theta = 0$ is reported below the table and has a $p \leq 0.001$, which suggests that the overall effect size is statistically significantly different from zero.

Table 3. Baseline characteristics of patients with COVID-19 in the eleven literatures

Study	Year of study	Country	Study type	No. Patient	Age	Male	Female	Incubation period	Clinical outcome	SS-Yes	SS-No	Lab.	Specimens
Zhenwei et al., 2020	[24] 2019	China	Retrospective	4	41	3	1	NA	Discharged	All	No	RT-PCR	swab
Chengcheng et al., 2020	[25] 2019	China	Case study	90	52	39	51	NA	Discharged	All	No	RT-PCR	swab
Yingxia et al., 2020	[2] 2019	China	Case study	12	38	8	4	7	Discharged	All	No	qRT-PCR	swab
Gemin et al., 2020	[3] 2019	China	Retrospective	95	50	52	43	NA	Discharged	All	No	RT-PCR	swab
Xiaoming et al., 2020	[9] 2019	China	Retrospective	131	50	63	68	NA	Discharged	All	No	RT-PCR	swab
Tao Chen et al., 2020	[26] 2019	China	Retrospective	548	60	342	206	NA	Discharged	All	No	RT-PCR	swab
Moran and Task Force, 2020	[9] 2019	Korea	Case study	28	43	15	13	3.9	No	All	No	NA	No
Yuanyuan et al., 2020	[27] 2020	China	Case study	62	79	40	22	28	Discharged	All	No	RT-PCR	swab
Anu et al., 2020	[28] 2020	Finland	Case study	1	30	0	1	23	serum	All	No	RT-PCR	swab
Iek et al., 2020	[29] 2020	China	Case study	10	46	3	7	25	sputum	All	No	RT-PCR	swab
Wang et al., 2019	[30] 2020	China	Clinical	114	53	58	56	NA	Discharged	All	No	RT-PCR	swab

Chest computed tomography (CT); Signs and symptoms (SS); Laboratory (Lab.), NA (Not Assigned), Real-Time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR)

We should be careful with our inferential conclusions about θ because of the presence of between-study heterogeneity, as indicated, for instance, by the homogeneity test of $H0$: $\theta 1 = \theta 2 = = \theta 11 = \theta$ reported the following significance test. Its Q statistic is 184.47 with $p \leq 0.001$, from which we can infer that there is significant heterogeneity between the individual studies.

The presence of heterogeneity among studies can be inferred also from the heterogeneity statistics reported in the header. For instance, $I^2 = 94.58$ indicates that about 95% of the variability in the effect size estimates is due to the differences between studies. The between-study heterogeneity must be addressed before the final meta-analytic conclusions we put about subgroup meta-analysis.

We obtain the same meta-analysis summary as in Meta summarized (Figure 1) in the above results, but it is now displayed on a graph. In addition to the estimated values, the effect sizes are displayed graphically as dark-blue squares centered at their estimates with areas proportional to the study weights and with horizontal lines or whiskers that represent the length of the corresponding CIs. The overall effect size is displayed as a green diamond with its width corresponding to the respective CI. (Notice that only the width and not the height of the diamond are relevant for the overall effect size.) A forest plot provides an easy way to visually explore the agreement between the study-specific effect sizes and how close they are to the overall effect size. We can also spot the studies with large weights more easily by simply looking at the studies with large squares.

Table 4. Summary pooled mean COVID-19 difference of RT-PCR

```
. meta summarize, random(dlaird)

  Effect-size label:  Log Odds-Ratio
        Effect size:  _meta_es
          Std. Err.:  _meta_se
        Study label:  study

Meta-analysis summary                       Number of studies =     11
Random-effects model                        Heterogeneity:
Method: DerSimonian-Laird                              tau2 = 23.7165
                                                    I2 (%) =   94.58
                                                       H2 =   18.45
```

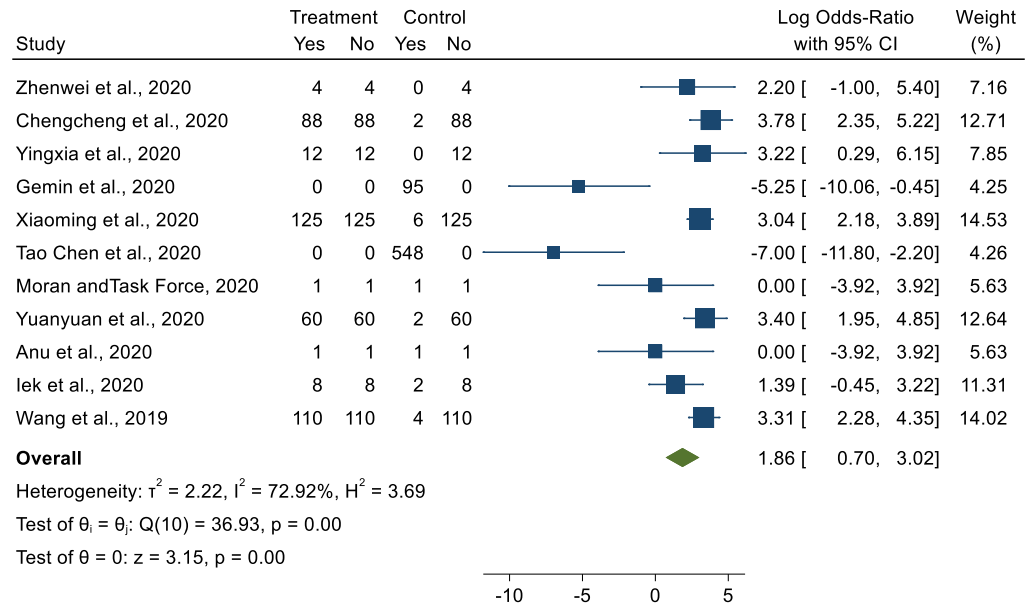
Study	Log Odds-Ratio	[95% Conf.	Interval]	% Weight
Zhenwei et al., 2020	4.394	0.262	8.526	8.47
Chengcheng et al., 2020	7.568	5.586	9.550	9.64
Yingxia et al., 2020	6.438	2.440	10.435	8.55
Gemin et al., 2020	-10.505	-14.435	-6.574	8.60
Xiaoming et al., 2020	6.073	4.915	7.232	9.91
Tao Chen et al., 2020	-14.001	-17.922	-10.079	8.60
Moran andTask Force, 2020	0.000	-3.920	3.920	8.60
Yuanyuan et al., 2020	6.802	4.810	8.795	9.63
Anu et al., 2020	0.000	-3.920	3.920	8.60
Iek et al., 2020	2.773	0.581	4.964	9.55
Wang et al., 2019	6.628	5.217	8.039	9.84
theta	1.719	-1.308	4.746	

```
Test of theta = 0: z = 1.11                      Prob > |z| = 0.2656
Test of homogeneity: Q = chi2(10) = 184.47         Prob > Q = 0.0000

. meta forestplot, random(dlaird)

  Effect-size label:  Log Odds-Ratio
        Effect size:  _meta_es
          Std. Err.:  _meta_se
        Study label:  study
```

Table 5. Forest plot indicating the pooled mean difference in COVID-19 suspected patients in full clinical parameters of RT-PCR and Chest computed tomography (CT)



Results of the test of homogeneity, sensitivity, and publication bias

Indicators of the test of heterogeneity/homogeneity (I^2=2.2% and p≤0.001) revealed that the studies were homogeneous. Tables 6 and 7 also described the sensitivity and regression of the result, respectively. All of these studies lied within the 95% confidence bound in DerSimonian-Laird plot, which confirms the homogeneity among the studies of publication bias and heterogeneity test (Figure 2 and Figure 3) respectively.

Indeed, if we look at the overall effect size estimates for each group, the COVID-19 with PCR test group has a larger estimate of 1.86 with a 95% CI of [0.70*;* 0.02], which suggests a statistically significant effect in this group, whereas the Non-PCR test group has a smaller estimate of p≤0.001 with a 95% CI of [-3.922*;* 3.92], which suggests that the effect in this group is not different from 0 at a 5% significance level. It is essentially exposed in the COVID-19 PCR group and is much smaller (for instance, I^2 = 2.22% versus the earlier I^2 = 79.92%) in the Non-PCR group. The test of group differences (with *Q10* = 36.93 and the corresponding (p≤0.001) reported at the bottom of the output also indicates that the group-specific overall effect sizes are statistically different in (Table 9).

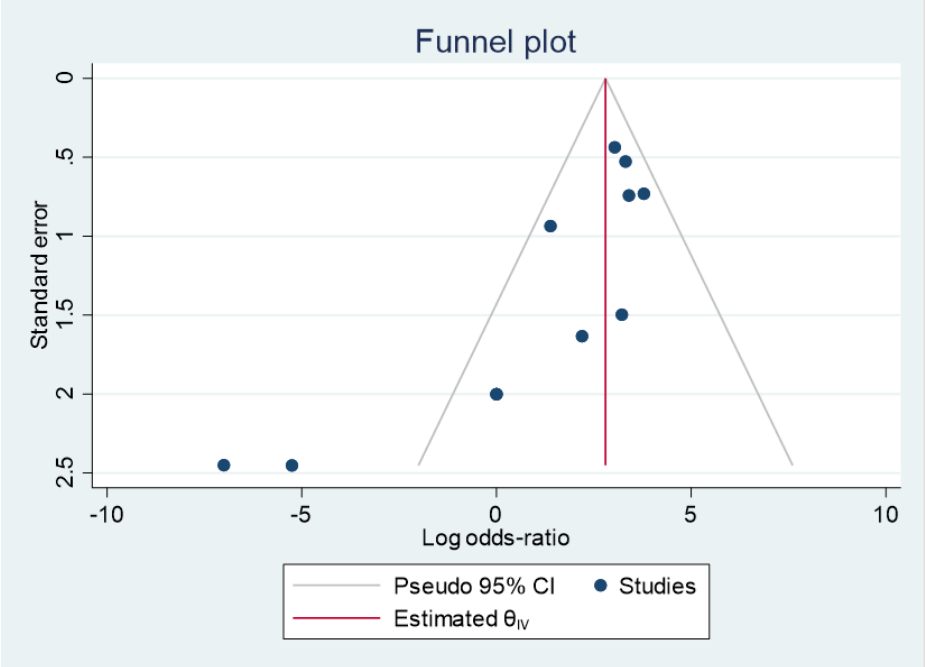


Figure 2. Funnel plot about publication bias

Table 6. Sensitivity meta-analysis

```
. meta regress _cons, random(dlaird)

  Effect-size label:  Log Odds-Ratio
        Effect size:  _meta_es
          Std. Err.:  _meta_se

Random-effects meta-regression                  Number of obs  =        11
Method: DerSimonian-Laird                       Residual heterogeneity:
                                                          tau2 =     2.219
                                                       I2 (%)  =     72.92
                                                          H2   =      3.69
                                                Wald chi2(0)   =         .
                                                Prob > chi2    =         .
```

_meta_es	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_cons	1.862372	.5916373	3.15	0.002	.7027845	3.02196

Test of residual homogeneity: Q_res = chi2(10) = 36.93 Prob > Q_res = 0.0001

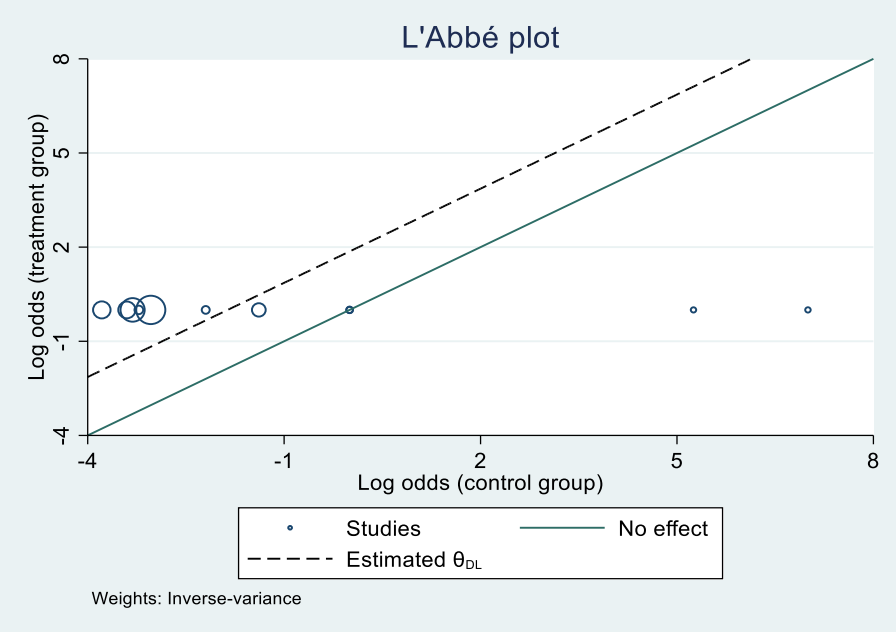


Figure 3. Heterogeneity

Table 7. The result of regression

```
Random-effects meta-regression                  Number of obs  =        11
Method: REML                                    Residual heterogeneity:
                                                          tau2 = 8.0e-07
                                                       I2 (%)  =     0.00
                                                          H2   =     1.00
                                                R-squared (%)  =   100.00
                                                Wald chi2(7)   =     35.76
                                                Prob > chi2    =    0.0000
```

_meta_es	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
yearofstudy	-1.013484	.7694577	-1.32	0.188	-2.521594	.4946251
nopatient	-.013995	.1166772	-0.12	0.905	-.2426781	.2146882
age	-.0294188	.018079	-1.63	0.104	-.064853	.0060154
covid19posative	-.1577663	.0715156	-2.21	0.027	-.2979344	-.0175982
pcr	.0605764	.1451932	0.42	0.677	-.2239971	.3451498
ctsuccesses	.1945793	.0980517	1.98	0.047	.0024014	.3867572
ctfailures	.1560072	.0964502	1.62	0.106	-.0330316	.3450461
_cons	2049.62	1554.373	1.32	0.187	-996.8952	5096.135

Test of residual homogeneity: Q_res = chi2(3) = 1.17 Prob > Q_res = 0.7599

Table 8. Sub-group analysis of the COVID-19 positive and PCR results

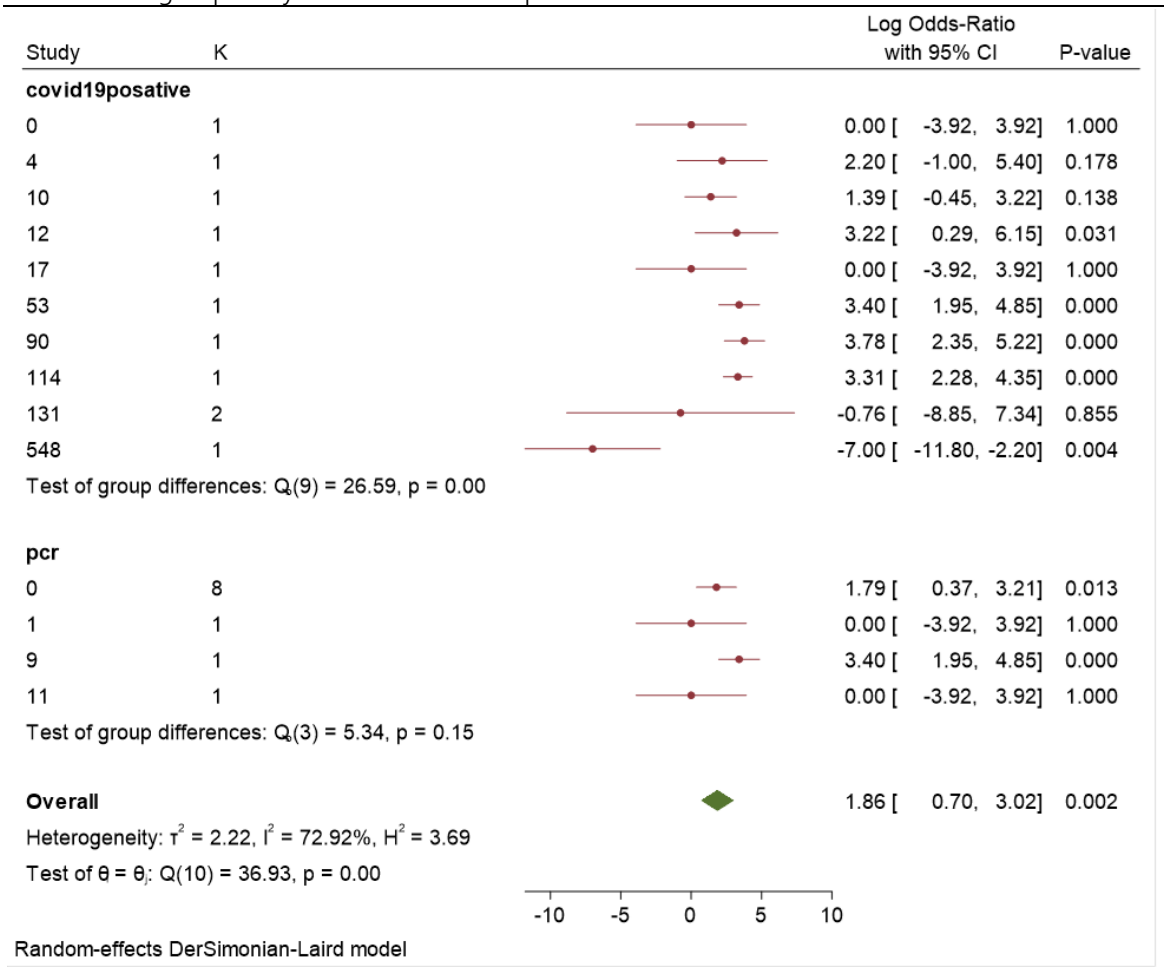
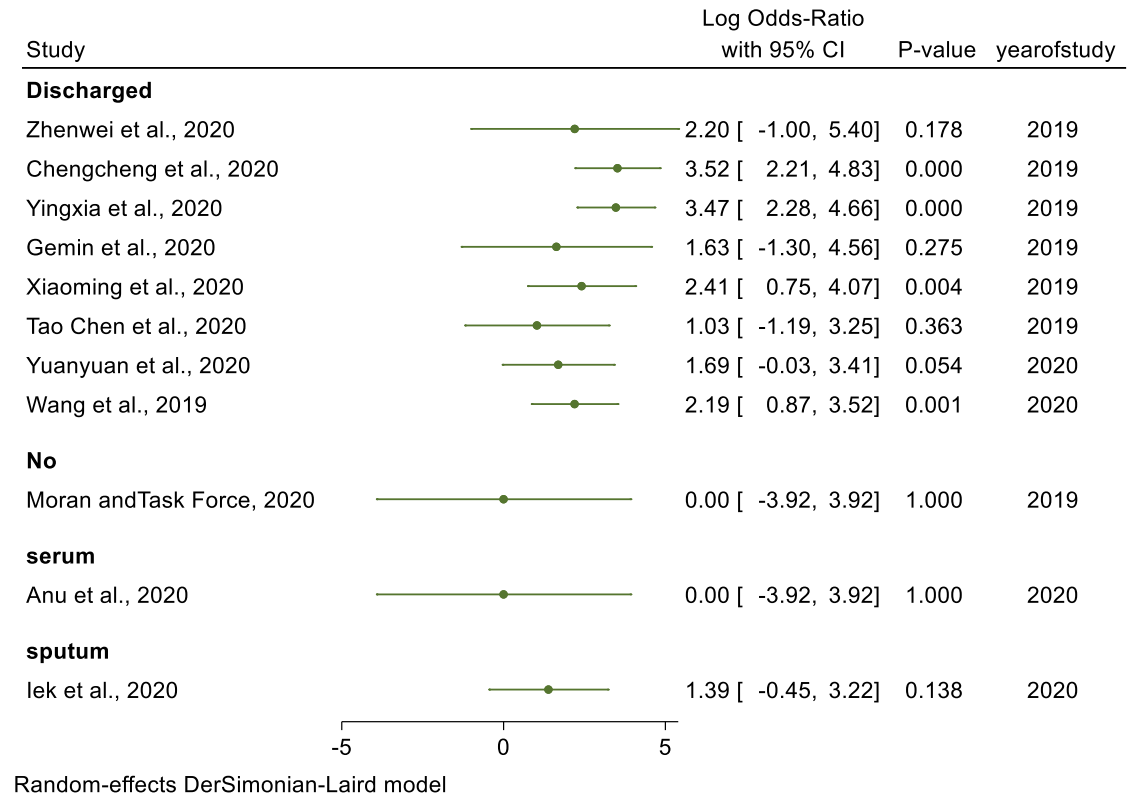


Table 9. Cumulative meta-analysis



DISCUSSION

The results of meta-analysis illustrated that suspected patients with COVID-19 result in (95% CI: -1-30; 4-74) increase in the diagnosis accuracy of RT-PCR compared to their counterparts taken Chest computed tomography (CT). Significant effect of multiple laboratory confirmatory mechanism's in the world is consistent with the former review reports comparing Chest computed tomography (CT) and other serological laboratory diagnosis mechanism's [31]. In line with the current finding, a systematic review and meta-analysis results revealed that RT-PCR are more than 99% increase in the accuracy of laboratory confirmatory and diagnosis mechanism's in the patients suspected with COVID-19 who were suspected with COVID-19 and similar patients to those who were suspected with COVID-19 and confirmed by any other serological detection and diagnosis mechanism's [32].

Finally, this review tried to generate pooled evidences, that examined the effect of RT-PCR and CT's to enhance the quality of studies by reducing bias (For instance, detection bias due to failure to blind outcome assessors, performance bias etc.) and confounding associated with observational studies. Nevertheless, the scarcity of literatures, failing to access articles published in other databases (like Embase), and restricting the search strategies to those published in English are some limitations of this review.

CONCLUSIONS AND RECOMMENDATIONS

In summary, COVID-19 suspected patient laboratory confirmation using RT-PCR and CT has significant and extra benefit in increasing the control and prevention mechanism of the spread of the virus to that of in place of other serological detection tests. As a result, this finding, is recommended to pilot and scale-up well and accurate laboratory techniques is used in developing countries, and is very important to prevent and control the pandemic diseases with spread in the world. However, it is recommended to further investigate the adverse effect of RT-PCR before fully implementing the confirmation.

DECLARATIONS

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Authors' contributions

The author designed the study, searched the database, extracted the data, and did the quality assessment. He did the statistical analysis and wrote the results section and assessed the quality of studies, wrote the initial draft, revised the paper.

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None.

Conflict of interest

All authors declare that they have no conflict of interest.

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