REVIEW ARTICLE

A systematic review and meta-analysis on efficacy of pooled serum versus commercial serum internal quality control in clinical biochemistry laboratory

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Abstract

Background: Internal Quality Control (IQC) is a critical operation that includes discovering analytical flaws during patient sample analysis to enhance the accuracy and reliability of test results and improve patient care. Scarcity and exorbitant expense of commercial IQC material disadvantage many developing nations. Pooled serum can be a potential alternate for IQC material. The study's goal was to assess the effectiveness of pooled serum and commercial IQC materials in clinical laboratory. *Material and Methods:* A comprehensive search was conducted for data published in hospital settings between 2019 and June 2024 using data sources like Cochrane, PubMed, and Google scholar. The published articles selected were all pooled serum compared with commercial IQC in terms of efficacy, stability & cost effectiveness. Studies with incomplete data for meta-analysis were excluded. The data extraction was done as per pre-established checklist. RevMan 5.4 software was used to analyse the odds ratio for the coefficient of variation of pooled serum and commercial IQC. *Results:* Seven relevant publications were included in meta-analysis that compared the biochemical parameters of creatinine, urea, glucose, aspartate transaminase, triglyceride, alanine transaminase, total protein, total bilirubin, Alkaline Phosphatase (ALP), albumin, cholesterol, albumin, cholesterol, and calcium between pooled serum and commercial IQC. Apart from ALP, which significantly affected IQC (95% CI 0.10-0.40, $P = 0.03$) with a p value < 0.00001, there was no statistically significant difference between pooled serum and commercial serum parameters, and a significant Q statistic showed the absence of heterogeneity ($I^2 = 0\%$). *Conclusion:* Our study found that the pooled serum performed better than commercial IQC in clinical biochemistry laboratory and also showed that in-house pooled serum had more stable biochemical characteristics than commercial IQC material.

Keywords: Internal Quality Control, Pooled Serum, Commercial Serum, IQC material, Clinical Biochemistry

Introduction

Internal Quality Control (IQC), is a critical operation that includes identifying analytical mistakes during patient sample analysis in order to improve the accuracy and reliability of test findings and patient care [1]. In medical laboratories, quality control is critical for tracking and evaluating the analytical technique that produces patient outcomes. Using these quality assurance approaches can help uncover errors and take corrective action [2]. Laboratory mistakes occur in three stages: pre-

analytical, analytical, and post-analytical [3]. Analytical variability can be monitored by IQC and external quality assessment systems, although pre-analytical and pro-analytical errors are more managerial issues. The primary goal of IQC is mostly to confirm the credibility of laboratory estimations with relation to time [4-6].

Erroneous results from the laboratory can result in poor management and even catastrophic outcomes. Nonetheless, scarcity and exorbitant expense of the commercial IQC material disadvantage many developing nations [6, 7]. According to NABL requirements, IQC should be performed at least twice each day, and using commercial IQC materials is more expensive. One of the downsides of commercial materials is that their composition fluctuates from one vial to the next. In addition, even with meticulous filling, reconstitution of the material may result in additional errors. Control materials derived from serum are referred to as pooled serum. This involves collecting and combining serum samples from various individuals or animals to form a single, uniform sample, which is then preserved with a solution (such as sodium azide or ethanediol). The pooled serum is stored in a freezer at temperatures of -20°C or -80°C until it is ready for analysis. [8, 9]. In few studies, no preservative was used [10, 11].

Commercial IQC, available in the lyophilized form or freeze-dried, were aliquoted and stored in freezer for further analysis. In various studies, an aliquot of pooled serum was analysed daily and consecutively for 20 or 30 days for commonly used biochemical parameters such as creatinine, urea, glucose, Aspartate Transaminase (AST), triglyceride, Alanine Transaminase (ALT), total protein, total bilirubin, Alkaline Phosphatase (ALP), albumin, cholesterol, albumin, cholesterol, and calcium [12-15]. We assessed the biochemical parameters to determine that the validity and reliability of pooled serum test results were better than those of commercial serum. Additionally, we evaluated the stability and cost-effectiveness of homemade IQC pooled serum, made from residual human serum samples, by comparing it with commercial IQC through a meta-analysis of published studies. Thus, the purpose of this meta-analysis was to compare the effectiveness of in-house pooled serum with commercial serum IQC material for ensuring the analytical quality in clinical biochemistry laboratories.

Material and Methods

The current study protocol was prospectively filed with PROSPEREO with the ID CRD42024569317. It was carried out strictly according to the reporting requirements specified in the "Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Guidelines" [15]. A meta-analysis was performed since the heterogeneity in the systematic review was within an acceptable range.

Eligibility criteria

The pooled serum's efficacy in comparison to commercial IQC was the criteria for selecting articles for this meta-analysis.

Inclusion criteria: Studies that have estimated the efficacy of homemade pooled serum in comparison with commercial IQC, studies that have assessed the stability & cost effectiveness of homemade IQC pooled serum from residual human serum samples compared with commercial IQC, studies that evaluated the pooled serum test result's validity and reliability was superior to that commercial serum IQC [8-14], and original research articles, including experimental, cross-sectional or cohort studies.

Exclusion criteria: Studies with incomplete data for meta-analysis which included reviews, editorials and conference abstracts without sufficient data.

Search strategy and study selection

Utilizing electronic retrieval methods, the literature was retrieved. Cochrane, PubMed, and Google Scholar were among the databases examined for the comprehensive and systematic evaluation of literature, which was conducted using a mix of Medical Subject Headings (MeSH) for studies through June 2024. Furthermore, a manual search of the major trial reference list was done using specified subjects, and the review and analysis comprised relevant publications. The research selection was conducted by inputting the search results into the online systematic review application Rayyan [16]. The selection of the studies was done by a two-step screening procedure. The literature search was conducted by two independent authors (K.S., S.B.), who also assessed each study's title, abstract, and keywords. Three authors (K.S., J.K., and S.B.) independently screened the abstract and full text to choose the papers that met our review's eligibility criteria. Any controversies or disagreements throughout the selection process were resolved by consensus or consultation with a fourth author (R.M.). If disputes arose among the reviewers, the fifth reviewer (J.F.) moderated a conversation to achieve consensus.

Data extraction and management

First and co-authors individually extracted the pertinent research features for the review from the included studies using outcome measures. A predetermined checklist served as a guide for data extraction, and Table 1 displays the extracted data, which comprised the first author's last name, publication year, study setting, study design, and study period, sampling strategy, parameters screened for and sample storage length. The first author (K.S.) entered data using Review Manager (RevMan5.4) [17]. The second author (J.K.) confirmed that the data was entered accurately by comparing it to the data included in the reports and presented during the review.

Outcome of the study

The results of the study were utilized to compare the cost, validity, stability, and reliability of pooled serum IQC to commercial serum IQC in clinical biochemistry laboratories using a meta-analysis of published papers. This study ensures analytical quality in clinical biochemistry laboratories.

Quality assessment of the study

The risk of bias in the selected studies was assessed using the Joanna Briggs Institute (JBI) technique [18], as shown in Table 2. All included papers were classified using JBI methodologies, with the exception of the Tewabe *et al.* research [9], which was not suitable for quality evaluation.The evaluation results were ultimately presented as follows: "Green" denoted "Yes," meaning the study satisfied the criterion; "Red" denoted "No," meaning the study did not meet the criterion; "Yellow" denoted "Unclear," meaning there was insufficient information to make a judgment; and "Grey" denoted "Not applicable," meaning the criterion was not pertinent to the study.

Table 1: Selected Studies Characteristics

First author	Screened for	Study setting	Study design	Duration	Sampling strategy	Comparison parameters	Sample storage duration	Results
Prasad *et al.* (2019)	HIV and HBV	Clinical Laboratory	Prospective analytical study	6 months	Purposive sampling	AST, ALT, ALP	20	The activity of ALP in pooled serum was stable when stored frozen at -20°C than commercial Quality control (QC)
Kulkarni *et al.* (2020)	HIV, HCV and HBsAg antibodies	Tertiary care hospital	Analytical study	3 months	Not mentioned	AST, ALT, ALP, urea, creatinine, glucose, total bilirubin, total protein, albumin, calcium, cholesterol, triglyceride	30	A significant difference between pooled serum and commercial QC was found
Jiskani *et al.* (2021)	Not mentioned	Tertiary care hospital	Analytical study	3 months	Not mentioned	AST, ALT, total bilirubin, direct bilirubin, calcium, ALP, glucose, urea, creatinine, cholesterol, total protein, albumin, triglyceride, amylase	30	In-house and commercial IQC has been found to differ significantly
Devi *et al.* (2023)	HIV, HCV and HBsAg	Clinical laboratory	Analytical study	2 months	Not mentioned	Glucose, calcium, phosphorus, sodium, urea, creatinine, total bilirubin, potassium, chloride, AST, total protein, ALT, ALP, albumin, cholesterol, triglyceride	20	There were analytical errors between biochemical parameters of pooled serum and commercial QC

Continued...

First author	Screened for	Study setting	Study design	Duration	Sampling strategy	Comparison parameters	Sample storage duration	Results
Sari *et al.* (2023)	HIV, HBV and HCV	Clinical laboratory	Comparati ve study	2 months	Purposive sampling	Triglyceride	30	Pooled serum and commercial serum showed a significant difference in triglycerides
Maharan a *et al.* (2024)	HIV, HbsAg and HCV	Tertiary care hospital	Experiment al study	1 months	Purposive sampling	Total bilirubin	30	The baseline means on the pooled serum and commercial QC differed significantly, although there was no statistical difference between the baseline and final means of the pooled serum's amber vial
Tewabe *et al.* (2024)	Not mentioned	Clinical laboratory	Cohort study	9 months	Purposive sampling	Glucose	30	For serum glucose, there was a substantial difference between commercial and in-house quality control

Note: ALP-Alkaline phosphatase; AST-Aspartate amino transferase; ALT-Alanine amino transaminase; HBsAg – Hepatitis B Surface Antigen; HCV – Hepatitis C Virus; HIV – Human Immunodeficiency Virus; HBV – Hepatitis B Virus

Table 2: Risk of bias

Cross-sectional studies	Prasad *et al.* 2019	Kulkarni *et al.* 2020	Jiskani *et al.* 2021	Devi *et al.* 2023	Sari *et al.* 2023	Maharana *et al.* 2024
Were the criteria for inclusion in the sample clearly defined?						
Were the study subjects and the setting described in detail?						
Was the exposure measured in a valid and reliable way?						
Were objective, standard criteria used for measurement of the condition?						
Were confounding factors identified?						
Were strategies to deal with confounding factors stated?						
Were the outcomes measured in a valid and reliable way?						
Was appropriate statistical analysis used?						

Note: Green – Yes; Yellow – Unclear; Grey - Not applicable; Red - No

Statistical analysis

A rigorous qualitative investigation was conducted on the biochemical characteristics of pooled serum and purchased serum IQC. Microsoft Excel was used to enter and compile the data. Statistical research was conducted using the RevMan 5.4 software [13]. Forest plots were employed to do a meta-analysis of biochemical markers for both group's IQC. The quantitative data and continuous variables were expressed using 95% Confidence Intervals (CI) for both study-specific and general pooled prevalence. I^2 statistics were used to examine heterogeneity. Statistically significant heterogeneity in the included studies was characterized as $p < 0.05$ or $I^2 > 50\%$. A sensitivity study was carried out to assess the accuracy of the meta-analysis estimate (Figure 2-13).

Results

Study selection and characteristics

Initially, twenty-nine studies were collected from databases. After duplicates were removed, twenty-two (record-screened) article abstracts were chosen. After excluding nine irrelevant studies, the remaining 13 underwent full-text screening. Six research papers were excluded owing to incorrect

study design or result. However, seven studies satisfied the inclusion requirements and were eventually included in the quantitative and qualitative assessment. Seven of these investigations evaluated the effectiveness of pooled serum to commercial IQC. Figure 1 depicts the research selection PRISMA diagram. All seven publications were completed in a clinical laboratory hospital environment [8-14].

Characteristics of the patient

All included investigations [8, 10-14] employed normal healthy patient samples for pooled sera, with the exception of Tewabe *et al.* 2024, which looked at diabetic patient samples [9]. Patients who tested negative for Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Surface Antigen (HBsAg), or HBV sickness had their remaining or residual serum collected in the included investigations [8, 10, 11, 13].

Methodology of the study

All seven publications included in the review concluded that pooled serum IQC was more successful than commercial serum IQC in clinical biochemistry laboratories. The chosen research was published in hospital settings from 2019 to 2024 [8-14]. Except for Tewabe *et al.* research [9], all the selected studies were analytical.

Comparing the biochemical parameters of serum internal quality controls

Serum glucose, serum urea, serum creatinine, total bilirubin, AST and ALT levels, total protein, albumin, cholesterol, triglycerides, calcium, and ALP levels were among the biochemical markers that were used to compare the pooled serum with commercial serum IQC materials. The meta-analysis comparing all the biochemical parameters between two groups IQC did not reveal statistically significant overall effect. The Odds Ratios (ORs) and corresponding 95% CI for each biochemical parameter are as follows:[OR 0.67 (95% CI 0.35-1.31), $P = 0.24$], [OR 1.65 (95% CI 0.73-3.70), $P = 0.23$], [OR 0.79 (95% CI 0.73-3.70), $P = 0.49$], [OR 1.12 (95% CI 0.40-1.55), $P = 0.73$], [OR 1.12 (95% CI 0.58-2.19), $P = 0.79$], [OR 0.86 (95% CI 0.41-1.83), $P = 0.70$], [OR 0.94 (95% CI 0.48-1.86), $P = 0.86$], [OR 0.85 (95% CI 0.39-1.86), $P = 0.69$], [OR 0.86 (95% CI 0.41-1.83), $P = 0.70$], [OR 0.62 (95% CI 0.24-1.64), $P = 0.33$], [OR 0.60 (95% CI 0.27-1.37), $P = 0.23$], and [OR 0.82 (95% CI 0.34-1.97), $P = 0.65$], except ALP parameter. The 95% CI for all biochemical parameters except ALP level crossed the line of no effect, indicating no significant difference between the two groups of IQC. However, the levels of biochemical parameters between those two groups showed absence of heterogeneity, as indicated by an I^2 value of 0% (Figure 2-7, 9-13). In a meta-analysis of ALP data, the pooled serum indicated a significant effect in favour of commercial IQC [OR 0.20 (95% CI 0.10 - 0.40), $P < 0.00001$]. A significant Q statistic revealed the presence of heterogeneity ($I^2 = 67\%$), implying significant heterogeneity among the included studies. The 95% CI does not intersect the line of no effect, as seen in Figure 8.

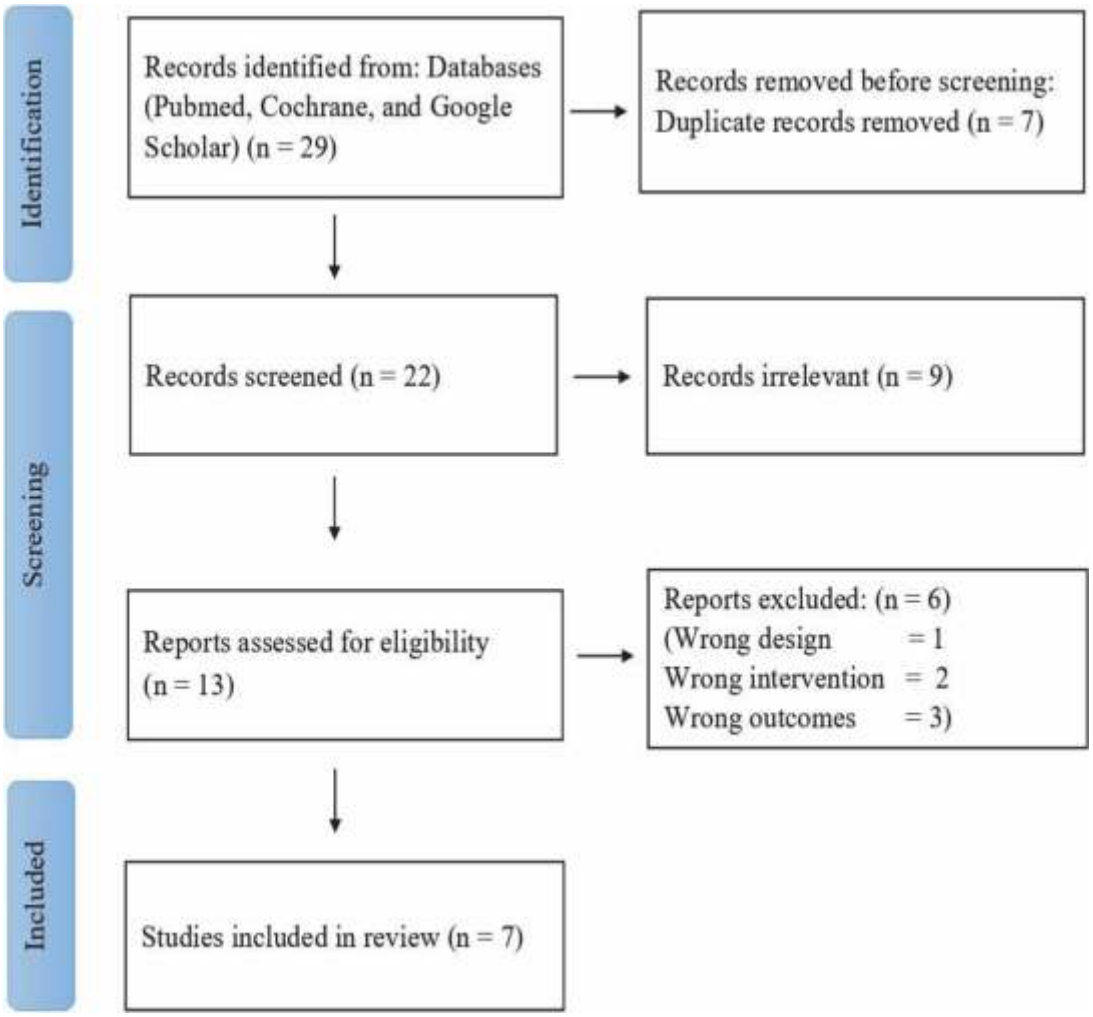

Figure 1: PRISMA study selection flow diagram

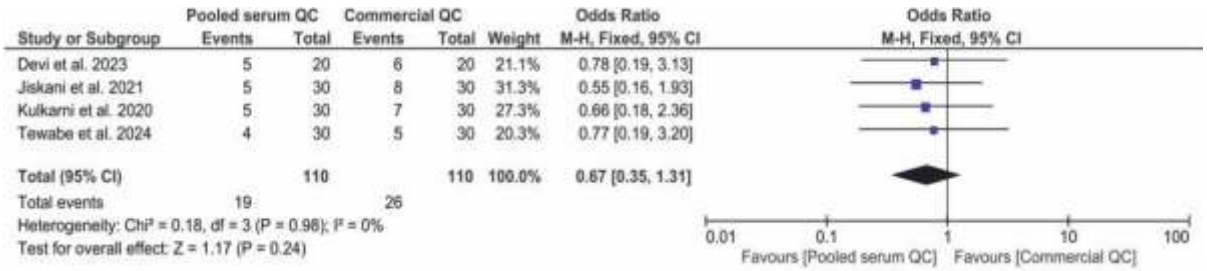

Figure 2: Comparison of pooled serum glucose levels with commercial IQC*

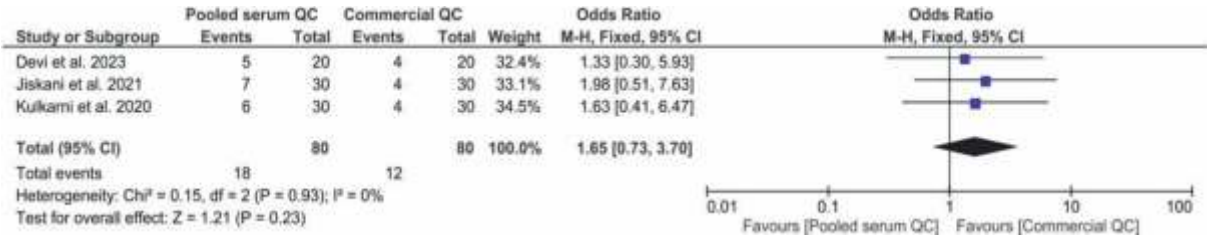

Figure 3: Comparison of pooled serum urea levels with commercial IQC*

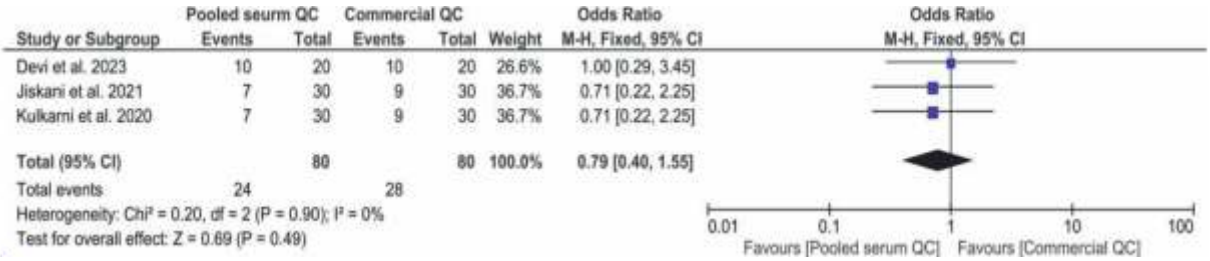

Figure 4: Comparison of pooled serum creatinine levels with commercial IQC*

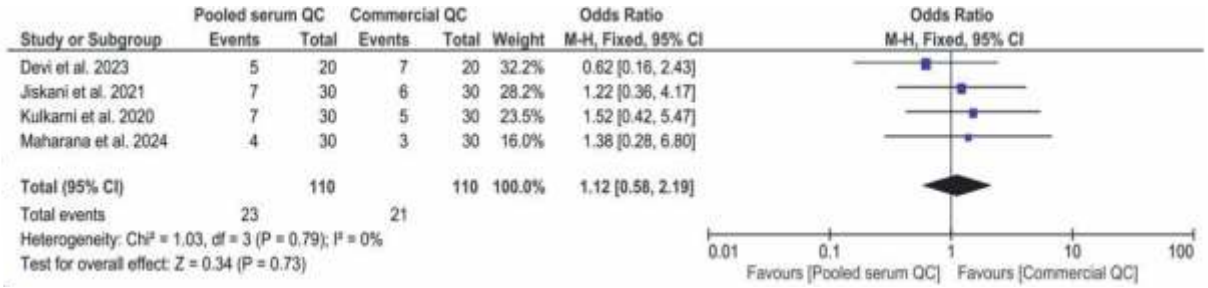

Figure 5: Comparison of pooled serum total bilirubin levels with commercial IQC*

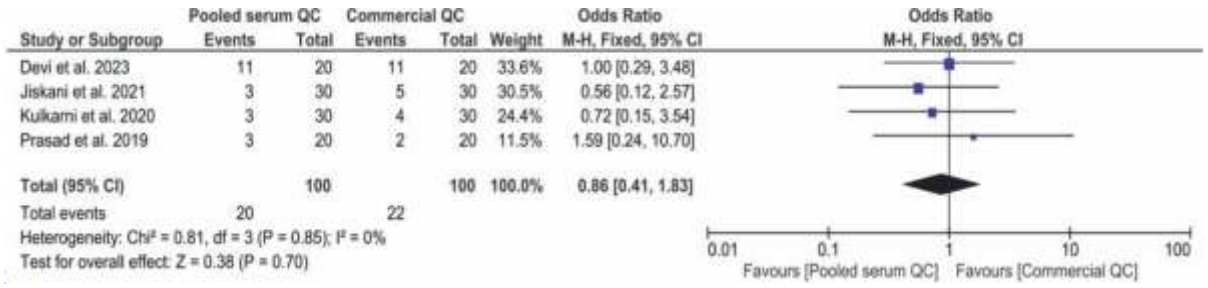

Figure 6: Comparison of pooled serum level of AST with commercial IQC*

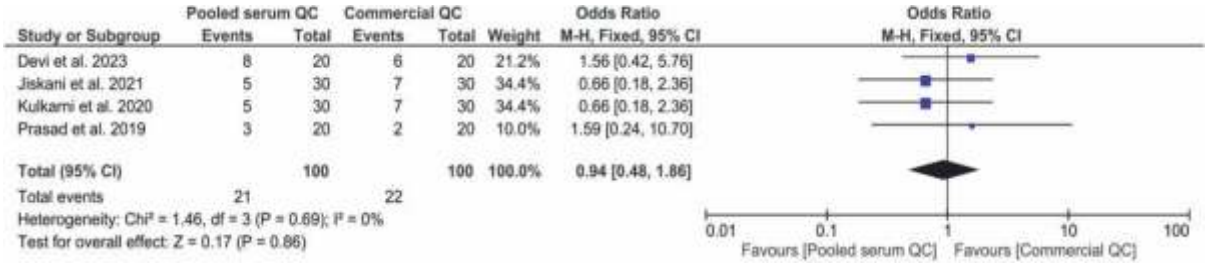

Figure 7: Comparison of pooled serum ALT levels with commercial IQC*

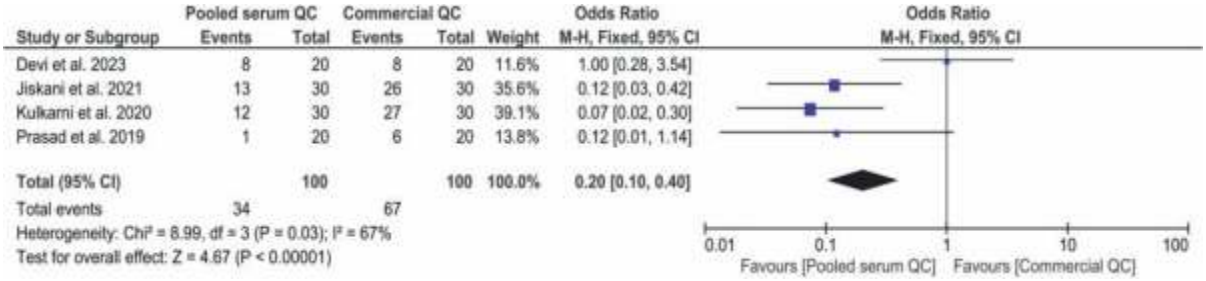

Figure 8: Comparison of pooled serum levels of ALP with commercial IQC*

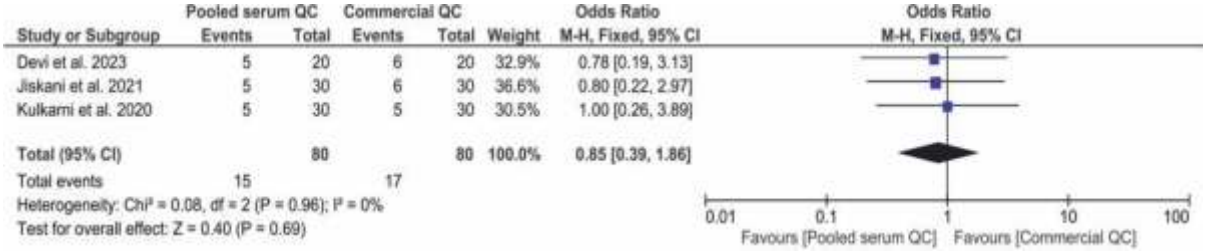

Figure 9: Comparison of total protein's pooled serum with commercial IQC*

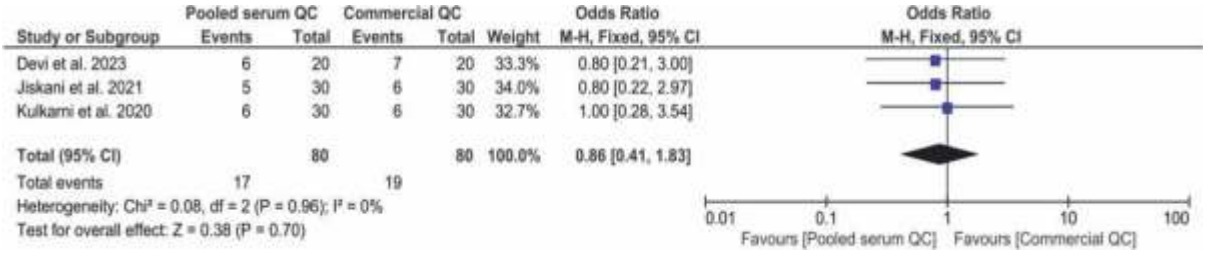

Figure 10: Comparison of albumin level of pooled serum with commercial IQC*

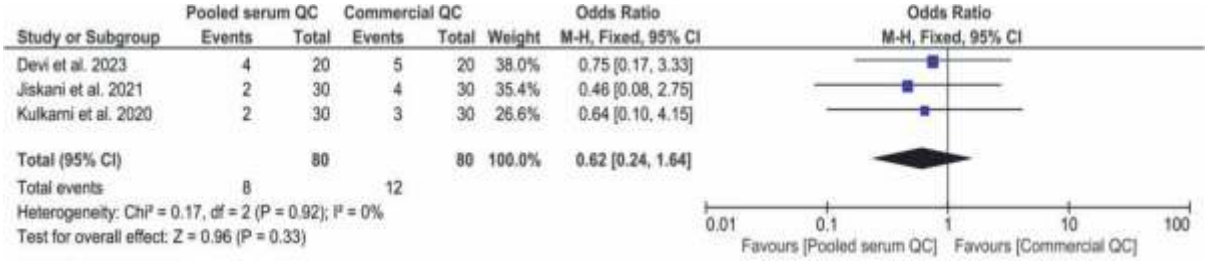

Figure 11: Comparison of pooled serum's cholesterol with commercial IQC*

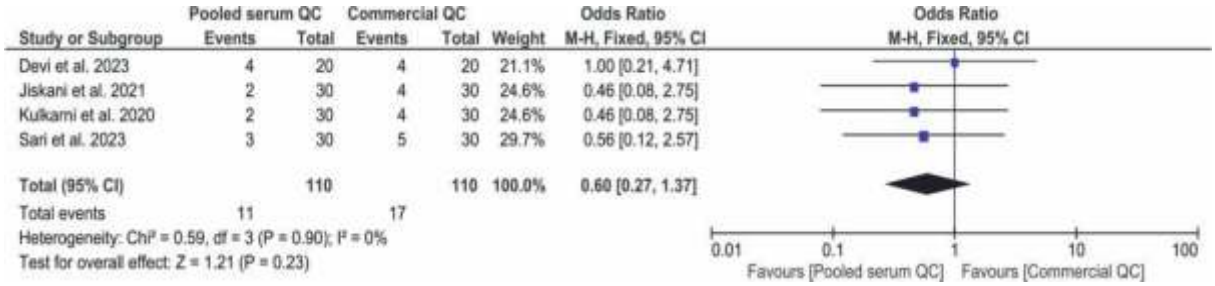

Figure 12: Comparison of pooled serum's triglycerides levels with commercial IQC*

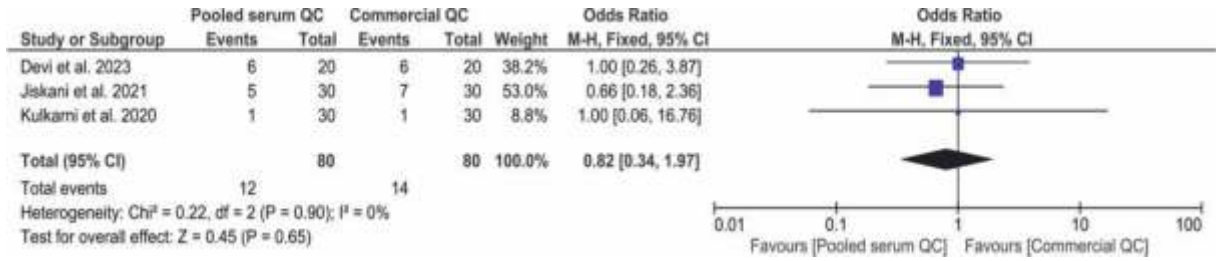

Figure 13: Comparison of pooled serum's calcium levels with commercial IQC
***CI: Confidence interval, Black diamond: Overall pooled effect**

Discussion

The meta-analysis included seven studies representing two groups: pooled serum and commercial IQC which included 12 biochemical parameters [8-14]. Meta-analysis showed that the CV% of glucose, total protein, creatinine, cholesterol, total bilirubin, AST, urea, ALT, albumin, triglyceride, and calcium were made from human pooled serum compared with commercial IQC was statistically not significant and 95% CI from the pooled estimate crosses the line of no effect. However, the meta-analysis of ALP data of pooled serum compared with commercial IQC had a statistically significant effect on IQC and 95 % CI did not cross the line of no effect. However, heterogeneity was shown in ALP (I^2 = 67%), suggesting substantial heterogeneity. Through meta-analysis, this study assessed the stability and effectiveness of pooled serum in clinical biochemistry labs in comparison to commercial serum IQC. The meta-analysis presented in this study also assessed the biochemical parameters for which validity and reliability of pooled serum test results were superior to that of commercial serum IQC. It is essential to monitor biochemical parameters for improving healthcare outcomes through precise and reliable laboratory test results. The key insights from our laboratory results are reinforced by this meta-analysis, contributing to the ongoing understanding of the efficacy of different IQC methods in clinical biochemistry [19-22].

According to a study by Jiskani *et al.*, pooled serum IQC is stable and more affordable than commercial serum IQC materials [12]. Using leftover blood samples from patients, Kulkarni *et al.* proved that pooled serum IQC had superior test result stability and validity than commercial IQC material [13].

Lalani *et al.* [23] showed that IQC developed from polycythaemia patients outperformed commercial IQC. Jamtsho *et al.* discovered that home-made lyophilized human serum is both stable and cost-effective for usage as a quality control material in Bhutan [24]. Tewabe *et al.* found that in pooled serum made for serum glucose, in-house QC components were more stable than commercial IQC material in clinical laboratories, demonstrating the potential of in-house serum from humans as a cost-effective and stable alternative to commercially generated control serum for glucose measures [9]. Anggra *et al* demonstrated that the results of triglycerides pooled sera material had more accuracy and precision when compared to commercial serum of the triglyceride examination [25]. An earlier study conducted by Khatri *et al*,

demonstrated a simple method of interpreting and analyzing the output to guarantee the reliability and validity of the pooled serum [26].

In tertiary care hospitals, thousands of samples are frequently received and examined. Clinical laboratories face numerous difficulties, including lack of quality control materials, lack of standard reagents, and equipment breakdown that can prevent the samples from being processed on the same day [27]. Benefits of the pooled human serum include simple preparation with the use of medical laboratory knowledge [28-30].

Limitations

Several limitations were identified in this investigation. The heterogeneity in technique, tools, and reporting standards across the selected papers may have an influence on the generalizability of our findings. Furthermore, the quality of the included research varied, and some had small sample sizes, which might affect the dependability of the results.

Conclusion

The meta-analysis study revealed that all biochemical parameters of pooled serum IQC when compared to commercial serum IQC were not statistically significant, with the exception of the ALP parameter, which had a substantial overall influence on quality control. Thus, the goal of this study was to evaluate the efficiency of in-house pooled serum with commercial serum IQC for assuring analytical quality in clinical biochemistry laboratories.

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