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Original Article

Comparative Evaluation of the Laboratory Efficiency before and after Total Lab Automation in Tertiary Care Hospital Laboratory in Pakistan

Ghazanfar Abbas[1], Qurat ul Ain[1], Imran Nazir Ahmed[1], Naveed Asif[2], Waqas Hanif[2]
Shifa International Hospital[1], Islamabad, Armed Forces Institute of Pathology[2], Rawalpindi.

Abstract

Background: Advance technology and diagnostic approach to disease has increased workload burden on laboratory and timely reporting as well as reliable results provision to physicians is another challenge of laboratory.
Objective: To compare pre-analytical errors, peak volume, flow rate and turn around time before and after total lab automation in clinical laboratory.
Study type, settings & duration: A cross-sectional study was carried out at Shifa International Hospital, Islamabad from January 2018 to December 2020.
Methodology: Present study assesses the key performance indicators based on the Total Lab Automation (TLA) work flow. Frequency and percentage was used to calculate increase in test volume before and after TLA implementation while one way ANOVA was used to test the difference in Turnaround Time (TAT).
Results: Prior TLA average turnaround time (TAT) for routine chemistry was 4 hours while immunoassay TAT average reported was 6-7 hours. Post TLA average TAT for routine chemistry is 1-2 hour while for immunoassay it 3-4 hours. There is 5-10% increase in test volume after the TLA implementation. TAT shows significant mean difference before and after TLA installation (*p* value=0.00).
Conclusion: In current study, findings prove that overall efficiency, turnaround time overall workload and optimize workflow occurred after implementation of TLA. Monitoring of key metrics help in continuous process improvement. Advance technology in laboratory makes work easier which was previously laborious.
Key words: Lab automation, turnaround time, peak hour factor, clinical laboratory.

Introduction

Laboratory plays an important role in diagnosis and prediction of many diseases. As medical care becomes advance and certain new markers are used for early disease identification and disease progression to improve quality of life.[1] It creates increased burden on laboratory, timely reporting as well as reliable results provision to physician is another dilemma for laboratory.[2] With the advance technology, laboratory automation now become cornerstone of many clinical and diagnostic laboratories and many decades witness the technological transition.[3] There are many phases for test processing which includes preanalytical, analytical and post analytical. Before introduction of total lab automation, all phases were dependent on human or manual interventions.[4] In TLA, an integrated system of all three phases preanalytical, analytical, and post analytical of testing process such as specimen or sample processing, centrifugation, analysis and even storage with minimal human involvement which ultimately help in improving the efficiency by reducing human error.[5] Due to constant pressure of ongoing work force and shortage of technical staff, TLA becomes an attractive solution that is expensive but effective and it is considered by many large core laboratories for future planning, growth and in line with required needs.[6] There are many options for TLA based on engineering innovation and practical trial and error. In this era of automation it is based on autoanalyser using continuous flow analysis that basically

Corresponding Author:
Qurat ul Ain
Shifa International Hospital,
Islamabad
Email: draaneiseera@gmail.com

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Authors Contribution

QA conceptualized the project. GA & QA did the data collection. INA did the literature search. NA performed the statistical analysis. Drafting, revision & writing of manuscript were done by QA & WH

automated the traditional manual procedure.[7] There are successive stand-alone analyzers increased analytical speed and able to produce high volume of test results of patient specimen and provides large test repertoire.[8] TLA affected on analytical phase but it also helped to reduce preanalytical errors like specimen identification, sorting and centrifugation and post analytical procedures such as specimen storage, retrieval and archiving. The new automated analyzers system includes an input/output module, processing, sorting, centrifugation, chemistry analyzer, immunoassays and refrigerated specimen storage area.[9] Current study was conducted with the objective of comparative assessment of laboratory key performance indicators before and after installation of TLA.

Methodology

In current study parameters used to assess is laboratory key performance indicators (KPIs) that are based on sample rejection due to preanalytical errors (haemolysis, lipemic and icteric, inappropriate transport or inappropriate tube usage) and turnaround time of parameters (urea, creatinine, glucose TSH, HBSAG, HCV and electrolytes), Archiving and post analytical errors. Key performance indicators collected from January 2018 to December 2020 from routine chemistry, immunoassay and haematology of clinical laboratory. We used Roche diagnostic TLA from Roche. Automated configuration is as follow:

1. Track Module
2. Input/output module
3. Bulk input module
4. Centrifuge module
5. Decapper and de sealer module
6. Refrigerated module for sample storage

TLA module was interfaced by two routine chemistry analyzer and two immunoassay equipment. Table-1 shows brief description of TLA and each component attached to it.

Data manager consist of software infinity and laboratory information system for reporting, technical validation. Total lab automation has been started in August 2019. Previously used Abbott modular system was used for routine chemistry and immunoassay. Data was extracted from lab management information system (LIS) from January 2018 to December 2020.

The ethical approval was obtained from Institutional Review Board (IRB) & Ethics Committee of Shifa International Hospital, Islamabad vide IRB # 112-21.

Results

Total number of test processed in January 2018 to December 2020 for chemistry analyte urea, creatinine, glucose fasting, based on immunoassay HBsAg, Anti HCV antibody, serum electrolytes sodium and potassium based on indirect ISE principle while CBC based on Conductimetry reported are detailed in Table 2 in which it showed that percentage of number of ALT, Creatinine ,sodium and potassium test increased in tenure of 2019-2020 is 17.8%,7.8%,8.4%,6.7% respectively.

TAT has been observed and data extracted from LIS before 2 month of TLA, after implementation and 2 month after TLA working. Prior TLA average TAT for routine chemistry was 4 hours while immunoassay TAT average reported was 6-7 hours.Post TLA average TAT for routine chemistry is 1-2 hour while for immunoassay it 3-4 hours.

After installation of TLA there was increase in total volume of test. Data was collected of 1st January 2018 to December 2020 which is shown in Figure-1 and in percentage shown in Table-2.TLA

Table 1: Description of TLA and associated components.

Module	*Description*	*Quantity*
Bulk Loader Module Cobas p 471	1. Length of tube including cap (min/max)= 72.1mm/108.0mm 2. Max 600 tubes and ensure clean and tightly closed cap.	01
Centrifuge unit Cobas p 471	1. System capacity 76 tubes per loading and centrifuge loaded and unloaded by gripper unit. 2. System compensates imbalance upto 40g and this is refrigerated centrifuge. 3. System has 14 free positions for racks each containing 19 tubes slots and 30 position racks for balance tube.	01
Input Sorter	Sample tubes are fed in at the input sorter and various tube carriers to the tube transporter system with the sorting unit.	
Roche Chemistry analysers	Based on photometry principle with module of indirect ISE	02
Roche immunoassay	Based on electrochemilumiscence	03

was installed in July 2019 and proper functioning start from September 2019.

Stat testing is an important part of hospital or clinical laboratory. Decision of critical cases depends on test report and laboratory deal those specimens as stat. Urgent testing is an important part of hospital or clinical laboratory for diagnosis and management of critical cases. Comparison of pre TLA and Post TLA stat and routine testing are shown in Figure-2.

One way Anova was run to check the mean difference of TAT timings of pre and post TAT timings for urea glucose and creatinine showed significant difference with *p* value<0.05 for all parameters except TSH which showed insignificant *p* value=0.763 while that for TSH was insignificant, Descriptive statistics of all parameters are shown in Table-3.

Patient identification and number of test is extreme importance for reliable and accurate results. Robotics has reduced number of errors related to patient identification due to bar code scanning. Overall 60-90% reduction of error occurred after integration of TLA and software. After installation of TLA work load of peak hour timings is increased as compared to pre TLA period. There is rise of 100% peak hour tube count in pre and post TA session. Figure-2 showed the graphical presentation of tube count in 24 hours of day where x axis is time, that number of tubes increase in 24 hours of day in TLA era as compared to pre TLA phase. In the figure 4 it has shown that number of tubes increase from 1100 hrs to 1300hrs which is considered as peak hour in hospital setting and in comparison to pre TLA number of tubes increased in TLA phase.

Peak hour factor (PHF) is used to convert the hourly volume into volume rate representing the busiest 15 min of hour and it ranges between 0.80-0.98, lower value signify greater variability of flow with in subject hour and higher value show little

Table 2: Frequency of test performed 2018-2020 and percentage increase.

Analyte	*Jan –Dec 2018*	*Jan-Dec 2019*	*Jan –Dec 2020*	*% increase from 2018-2019*	*% increase from 2019-2020*
ALT	5556	6181	7278	11.2	17.8
Serum. Creatinine	14666	15817	16360	3.4	7.8
S. Sodium	9911	10751	11308	5.1	8.4
Potassium	11461	12236	12413	1.5	6.7
HbsAg	2306	2364	2416	2.2	2.5
Anti HCV	2265	2366	2414	2.0	4.5
Vitamin D	1397	1600	1699	6.1	14.5

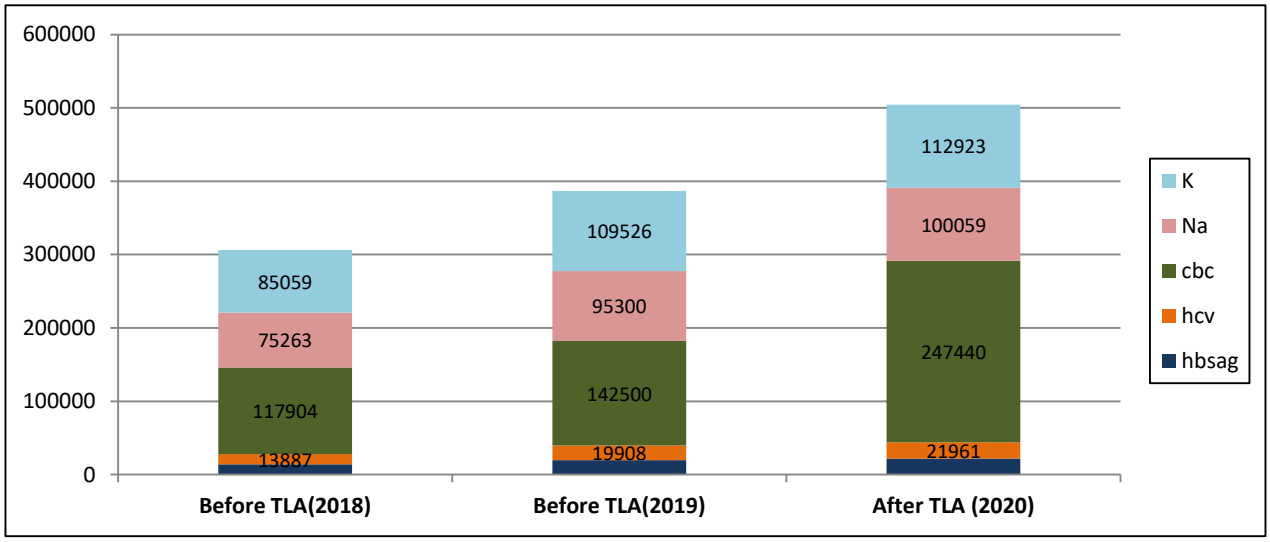

Figure 1: Comparative analysis of work flow of last Three years.

Table 3: Descriptive statistics and One way Anova for quantitative variables.

		N	Mean±SD	95% Confidence Interval for Mean		p value (0.05)
				Lower Bound	Upper Bound	
Urea_TAT18	Before TLA	40	3.10±0.54	2.9256	3.2744	0.00
	after TLA after 2 month	40	1.50±0.50	1.3381	1.6619	0.00
	Total	80	2.30±0.95	2.0864	2.5136	
Creatinine_TAT	Before TLA	40	2.60±1.21	2.2113	2.9887	0.00
	after TLA after 2 month	40	1.20±0.40	1.0704	1.3296	0.00
	Total	80	1.90±1.14	1.6456	2.1544	
Glucose_TAT	Before TLA	40	2.70±1.11	2.3437	3.0563	0.00
	after TLA after 2 month	40	1.30±0.46	1.1516	1.4484	0.00
	Total	80	2.00±1.10	1.7547	2.2453	
TSH_TAT	Before TLA	40	4.10±1.46	3.6318	4.5682	0.763
	after TLA after 2 month	40	4.20±1.48	3.7240	4.6760	0.755
	Total	80	4.15±1.46	3.8234	4.4766	

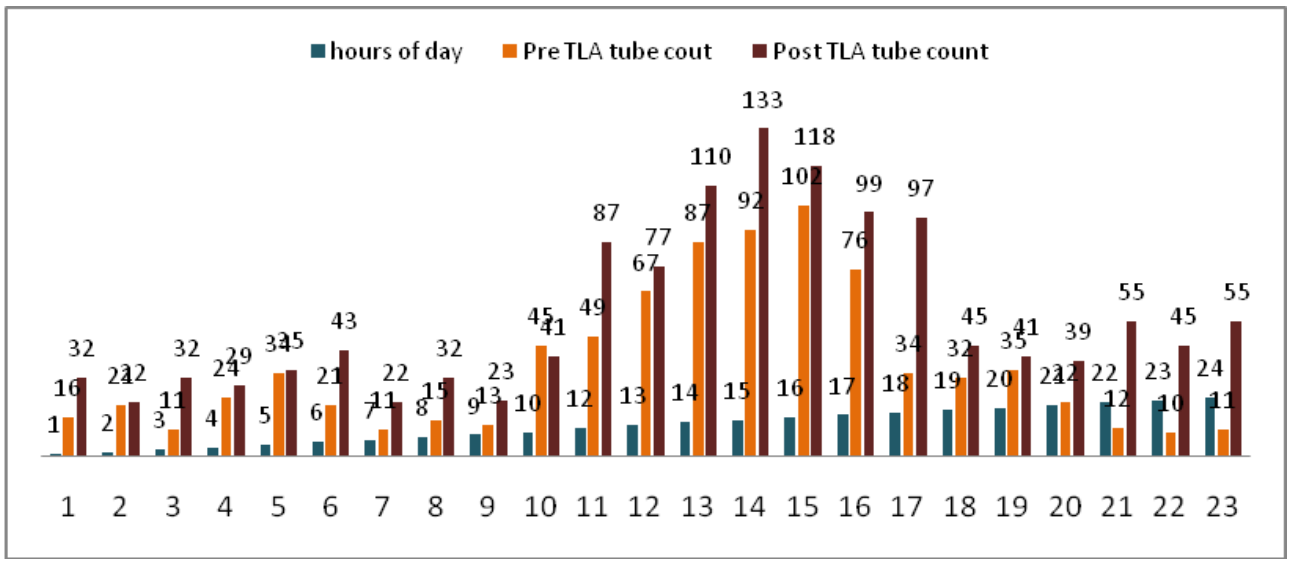

Figure 2: Number of peak hour tube and time count pre and post TLA Era.

variation, peak hour factor (PHF) with 0.73 showed that there is variability in test volume while after TLA peak hour factor is 0.83 and showed that peak hour volume is consistent. PHF and peak hour utilization are shown in Table 4in which Peak hour factor is calculated by dividing peak hour volume (workload when there is increase outpatient checkups) with peak 15 minutes volume (number of tubes or specimen received in laboratory). While peak hour flow rate peak hour volume/peak hour factor and it gives flow rate mean 300 tubes in one hour before TLA and 463 tubes or specimen per hour after TLA which shows that there is increased workload after TLA because of short TAT. Peak hour before and after TLA was same as it is same hospital setting I which flow rate increased and it leads to increase utilization about 71% as it shorten the duration of analysis and manual work that's why increased utilization as compared to pre TLA phase.

Discussion

In current study TLA era of Shifa laboratory compared with non TLA era of laboratory. It has been found that pre analytical errors reduced due to TLA integration and interfacing.[10] TLA integration can leads to profound impact on lean management and quality of work[11] which showed in current study that peak flow rate increase up to 463 which correlate with the findings of DR G et all published in 2010 and showed that peak flow rate increase markedly after installation of TLA.

Our study shows increase in volume of test from Jan 2018 to Jan 2020 is 5556 test in Jan 2018 while 7278 test which is 7.8% and 11.2 % for ALT, and similarly increase percentage of volume of test for HBsAg 2.2%, serum creatinine 3.4%, electrolytes including sodium and potassium 5.1% and after implementation of TLA which correlate

with the study findings by T. Minghong et al published in 2010[12] in department of clinical laboratory which shows increase in volume of test before and after TLA that is increase of 37.44% from 2017 to 2019 for immunology and up to 72.23% increase in chemical pathology.

Current study showed that peak hour utilization after TLA is 71% while before TLA peak hour utilization was 44% which also correlate with study findings by Zaninotto M et al 2010[13] that peak hour utilization after optimization is increase upto 81% which is higher than current study because of larger sample size and longer duration of follow up after integration and optimization of TLA.

The study conducted by Wang LC et al 2008 showed their findings that TAT has reduced from 6 hours to 2.5hours which correlate with current study findings that showed that TAT reduce after TLA integration up to 3 hours for routine testing for clinical biochemistry profile while for stat testing it reduce to 30- 60minutes.[14]

From analyzing data at different occasion before and soon after TLLA observed that TAT has significantly reduce and shorter than before. Peak hour collection data has observed after TLA implementation and it is considered time span for peak hour increased after optimization while peak hour utilization is also increased after TLA. In addition with support of better data manager an information system infinity we can monitor sample on system.[15] The advantages of automatic analysis are well known and can affect quality work of laboratory and deal with large volume of test. Current study needs to be multi-centered to asses' outcome of advance technology for laboratory sciences.

In current study, findings prove that overall efficiency, turnaround time overall workload and optimize workflow occurred after implementation of TLA. Monitring of key metrics help in continuous process improvement. Current study showed that there is reduction of 60-70% pre analytical rate, turnaround time 90% improved while post analytical errors reduced upto 80%. Advance technology in laboratory makes work easier which was previously laborious.

Conflict of interest: None declared.

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