

Analysis of Alcohol Concentration and Cost Variation of Different Laboratory Made and Commercially Available Hand Sanitizers Used in Corona Virus Disease Pandemic

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Abstract:

Background: Corona virus disease (COVID) emerged as pandemic outbreak affecting most of the countries worldwide. Hand hygiene was advised as preventive measure other than face covering. This study emphasized on the alcohol concentration and cost variation analysis of different laboratory made and commercially available hand sanitizers used in COVID pandemic.

Methods: This prospective, descriptive analytical study including laboratory procedure was conducted in the Department of Pharmacology, Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar for two months. Different sanitizers were assessed for the concentration variation in alcohol. Cost disparity was also analyzed between laboratory based and commercial preparations.

Results: Isopropyl and ethyl alcohol were found to be very effective agents against microbial bacteria, fungi, and viruses, ranging between 70% and 90% alcohol concentration. Observed concentration merely altered than expected concentration in most of the laboratory based and commercial branded (mean diff. value in the range 0.33-1.33, $p < 0.05$) whereas locally made sanitizer (mean diff. value in the range 0.5-6.17, $p > 0.05$) and herbal sanitizers (mean diff. value in the range 0.33-4.67, $p > 0.05$) were shown with relatively more variation. Price valuation suggested that laboratory made sanitizers were more cheaper than individual ingredients estimated cost and no price change was noticed in commercial sanitizers as their prices were fixed and controlled by government in public interest.

Conclusion: The study concluded that alcohol concentration variation was found in most of commercially available hand sanitizers and cost can be minimized in public interest. Manufacturing companies need to be prepared clinically effective cheaper sanitizers to ensure prevention of severe and rapid transmission of airborne infectious diseases like COVID in the developing countries like India.

Keywords: Corona virus disease (COVID), Isopropyl alcohol, Ethyl alcohol, Hand sanitizer, Concentration variation, Cost disparity.

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Introduction

Pandemic outbreak of COVID 19 (Corona Virus Disease 19) in the opening months of year 2020 and second waves in year 2021, springed up worldwide serious health concerns impending huge economic collapse as well. As per record updated in April 2024, there were a total of ~70.47 million reported COVID cases including ~7.01 million deaths (0.995%) and 34,794 serious or critical cases affecting over 231 countries and territories

worldwide.[1] India emerged as second largest country after United States of America accounted ~4.5 million corona affected cases with 5.34 lac deaths (1.84%), much higher than global data.[1] Hand washing is considered the best measure to avoid the transmission of harmful pathogens.[2] It helps to maintain hand hygiene and prevent health care associated infections. But it isn't always practical, however, especially for healthcare

workers. It includes various reasons like need for frequent hand disinfection, busy schedule or possible mental or physical rush and lack of access to tap water to wash the hands thoroughly.[3] Hand sanitization is considered among most commonly used hygiene practices to prevent infection and pathogenic transmission in current scenarios.[4] Evidence suggests that hand sanitization significantly reduces the transmission of pathogens and incidences among healthcare ecosystem.[5] Hand Sanitizer has a significant bacteriostatic effect on the hands surface and on the surface of inanimate objects.[6] According to Global market insight reports published on January 2023; hand sanitizer market size was worth more than USD 3.5 billion in 2022 and is estimated to grow at over 7% compound annual growth rate (CAGR) from 2023 to 2032 driven by the rising prevalence of infectious disease worldwide.[7] COVID outbreak brought about significant impact over consumer's behaviour to maintain their personal hygiene, especially hand hygiene which is foremost essential to prevent its transmission. People are being aware through news and public notices to frequently use hand sanitizer to avoid getting contracted with corona virus infection unknowingly.[8] Due to COVID pandemic, the Government initiatives to promote the use of hand sanitizer as a method of primordial prevention significantly boost the market growth. Progressive worsening situation of COVID-19 and back in year 2021 pandemic and its robust transmissible nature, the governments of various countries were providing infrastructure and funds to ramp up hand sanitizer production. Different formulations of hand sanitizers including alcohol, non-alcohol based or herbal sanitizers in liquid or gel consistency are being marketed. According to study done by Fendler et al. an alcohol gel hand sanitizer was found to decrease infection rate and provided an additional tool for effective infection control.[9] Previously few companies were only licensed and were associated with manufacturing and packaging of hand sanitizers. But rising demand for hand sanitizer in the market and to cope-up with the shortage in some areas, the government paved a path to emerge many local brands to reduce the demand crisis and to expedite the supply chain of hand sanitizers in India. Government is also providing easy authenticity passage and permission to new entrants for production of hand sanitizers with strict price limitation regulation. Overall goal is to assert that the use of hand sanitizer is one of the best precautionary measures available against the corona virus till present.

Aims and Objectives

Primary Objectives:

1. To evaluate and compare alcohol concentration of different laboratory based and commercially available hand sanitizers.
2. To evaluate disparity in cost of different laboratory made and commercially available hand sanitizers.

Secondary Objectives:

1. To spread awareness about effective concentration of alcohol to be used in hand rubs essentially need for proper sanitization.
2. To apprise about price disparity in different laboratory made hand sanitizers or those available in the Indian market.

Inclusion Criteria: Different concentration of alcohol irrespective of other constituents in hand sanitizers were included to analyse any variation. Both liquid and gel based commercial preparations of hand sanitizers manufactured by only licensed companies were included for price variation study.

Exclusion Criteria: Gel form sanitizers were excluded for the alcohol concentration variation analysis. Non-alcohol based sanitizers, illegally made and misbranded hand sanitizers were identified and excluded from this study.

Material and Methods

This prospective, observational study including laboratory procedure was conducted in the Department of Pharmacology, Narayan Medical College and Hospital, Jamuhar, Sasaram, Bihar for a period of two months.

Alcohol concentrations of different sanitizers were estimated in pharmacy lab after preparing alcohol based liquid sanitizers with different composition according to recommended authentic guidelines for practical purposes only. Other than laboratory samples, commercially available alcohol based liquid sanitizers of local and branded companies were also included in this study to compare their findings (Table 1). Various hand sanitizers with different alcohol concentration were collected from market and tested for alcohol concentration using six different alcohol-hydrometers or glass alcoholometers manufactured by JK Scientific Ltd., Ambala Cantt., Haryana. The hydrometers were used for reading the alcohol concentration of each sample of liquid for six readings for every sanitizer sample in standard laboratory condition at around 15-160 c of temperature. The mean difference between observed means and expected means were noted for different sanitizers of laboratory made samples and commercially available samples of sanitizers. One sample t-test was applied to estimate mean difference and p- value using IBM SPSS Version 20 software. Cost disparity was also analysed by calculating cost difference, cost ratio

and percentage price variation among laboratory based and other commercial preparations.

1. Estimation of concentration variation:

Observed means were calculated after averaging six reading using alcoholometers for each sample of sanitizer.

Mean differences were calculated as: Mean difference: Expected mean - Observed mean

Percentage concentration variations were estimated by formula:

% Concentration Variation = (Expected mean - Observed mean) / Observed mean x 100

2. Estimation of price variation:

- Cost of a particular sanitizer (cost per fixed volume of 500 ml) made in the laboratory in differential strength and composition were calculated by taking the minimum cost price of each ingredient on an individual basis which was further summed up with packaging cost to yield final price. Also, the printed costs in Indian Rupees (INR) of hand sanitizers available in the market were noted.
- Difference between the maximum and minimum cost price of the similar volume of different sanitizers was calculated.
- The cost ratio, the ratio of the maximum legalised price vs minimum cost price either laboratory made or commercially available

was calculated. This tells, how many times costliest the maximum selling price than the minimum approached cost in each category for the similar volume of each sample (Table 2).

- Percentage Price Variation was calculated using formula:[10]

% Price Variation = (Maximum price - Minimum price) / Minimum price x 100

Results:

Data from different sources were collected to see concentration and price variation based on different volume, concentration and chemical composition of sanitizers available from online sanitizer dealers and regional sanitizer retailers or distributors. Minimum variations in concentration were mostly seen in laboratory made and branded sanitizers followed by locally available sanitizers. But all sanitizers had concentration ranges within therapeutic value of 60-95% which was established as an effective concentration range for hand sanitizers as also notified by Centres for disease control and prevention (CDC) of India. [11, 12] Various parameters for analysis of alcohol concentration and cost variation of different laboratory based and commercially available hand sanitizers were described in Table 1 and 2 respectively.

Table 1: Description of Concentration based analysis of various hand sanitizers (coded samples with serial numbers to laboratory made and commercially available hand sanitizers)

Sl. NO	Composition of various hand sanitizer	Expected Conc.	Observed Conc.	p-value	Mean Difference	% Variation
A. Laboratory made liquid hand sanitizer						
L1	Isopropyl alcohol 75% +Hydrogen peroxide 3% + Glycerol 98% + Distilled water	75	74.33	0.102	0.67	0.897
L2	Isopropyl alcohol 75% +Hydrogen peroxide 3% + Distilled water	75	74.50	0.203	0.50	0.671
L3	Ethyl alcohol 80% + Hydrogen peroxide 3% +Glycerol 98% + Distilled water	80	79.50	0.076	0.50	0.629
L4	Isopropyl alcohol 75%+ Distilled water	75	74.67	0.175	0.33	0.446
L5	Isopropyl alcohol 70%+ Distilled water	70	69.33	0.042	0.67	0.962
L6	Ethyl alcohol 70 %+ Distilled water	70	69.33	0.102	0.67	0.962
L7	Ethyl alcohol 80 %+ Distilled water	80	79.67	0.175	0.33	0.418
L8	Ethanol 70% + Chlorhexidine 0.5% + Distilled Water	70	68.67	0.103	1.33	1.942
B. Commercially available liquid hand sanitizer(Branded)						
CB1	Hand rub (Ethanol based 85%)	85	83.50	0.001	1.50	1.796
CB2	Hand rub (Ethanol based 80%)	80	79.67	0.175	0.33	0.418
CB3	Handrub (Isopropyl alc. Based 85%)	85	83.67	0.002	1.33	1.594
CB4	Hand rub (Isopropyl alc. based 80%)	80	79.50	0.203	0.50	0.629

CB5	Hand rub (Isopropyl alc. based 75%)	75	74.83	0.363	0.17	0.223
CB6	Hand rub isopropyl alc. based 70%)	70	69.67	0.175	0.33	0.478
C. Commercially available liquid hand sanitizer(Local)						
CL1	Hand sanitizer (Ethyl alcohol based 70%)	70	65.83	0.001	4.17	6.329
CL2	Hand sanitizer (Ethyl alcohol based 83.33%)	83.33	80.33	0.003	3.00	3.730
CL3	Handrub (Ethanol 70% + Chlorhexidine 0.5%)	70	64.50	0.001	5.50	8.527
CL4	Handrub (Ethanol 75% + Chlorhexidine 0.5%)	75	68.83	0.001	6.17	8.959
CL5	Handrub (Propranolol based 70%)	70	66.33	0.025	3.67	5.528
CL6	Handrub (Propranolol based 75%)	75	74.50	0.076	0.50	0.671
D. Commercially available liquid hand sanitizer (Herbal)						
CH1	Herbal hand sanitizer (Isopropyl alcohol based 70%)	70	65.33	0.001	4.67	7.143
CH2	Herbal hand sanitizer (Ethyl alcohol based 75%)	75	74.67	0.174	0.33	0.446
CH3	Herbal hand sanitizer (Ethyl alcohol based 80%)	80	77.50	0.007	2.50	3.226
Laboratory, CB: Commercial Branded, CL: Commercial Local, CH: Commercial Herbal						

Table 2: Cost evaluation of laboratory made and commercially available hand sanitizers (500 ml)

Sl. No.	A. Laboratory made hand sanitizer	Minimum cost(Rs.)	Maximum cost(Rs.)	Cost Difference	Cost Ratio	% Variation
A1	Isopropyl alcohol 75% +Hydrogen peroxide 3% +Glycerol 98% +Distilled water	72.23	250	177.77	1:3.46	246.12
A2	Isopropyl alcohol 75% +Hydrogen peroxide 3% + Distilled water	73.41	250	176.59	1:3.41	240.55
A3	Ethyl alcohol 80% +Hydrogen peroxide 3% +Glycerol 98% +Distilled water	89.30	250	160.70	1:2.80	179.96
A4	Isopropyl alcohol 75%+Distilled water	67.75	250	182.25	1:3.69	269.00
A5	Isopropyl alcohol 70%+Distilled water	66.10	250	183.90	1:3.78	278.21
A6	Ethyl alcohol 70 %+ Distilled water	75.90	250	174.10	1:3.29	229.38
A7	Ethyl alcohol 80%+ Distilled water	79.60	250	170.40	1:3.14	214.07
A8	Ethyl alcohol 70 %+ Chlorhexidine 0.5% + Distilled water	75.78	250	174.22	1:3.30	229.90
B.	Commercially available hand sanitizer	250	250	0	1:1	0

Disparity in price (INR) for 500 ml and percentage variation of between laboratory made and commercially available hand sanitizers were also depicted through bar graph (fig.1).

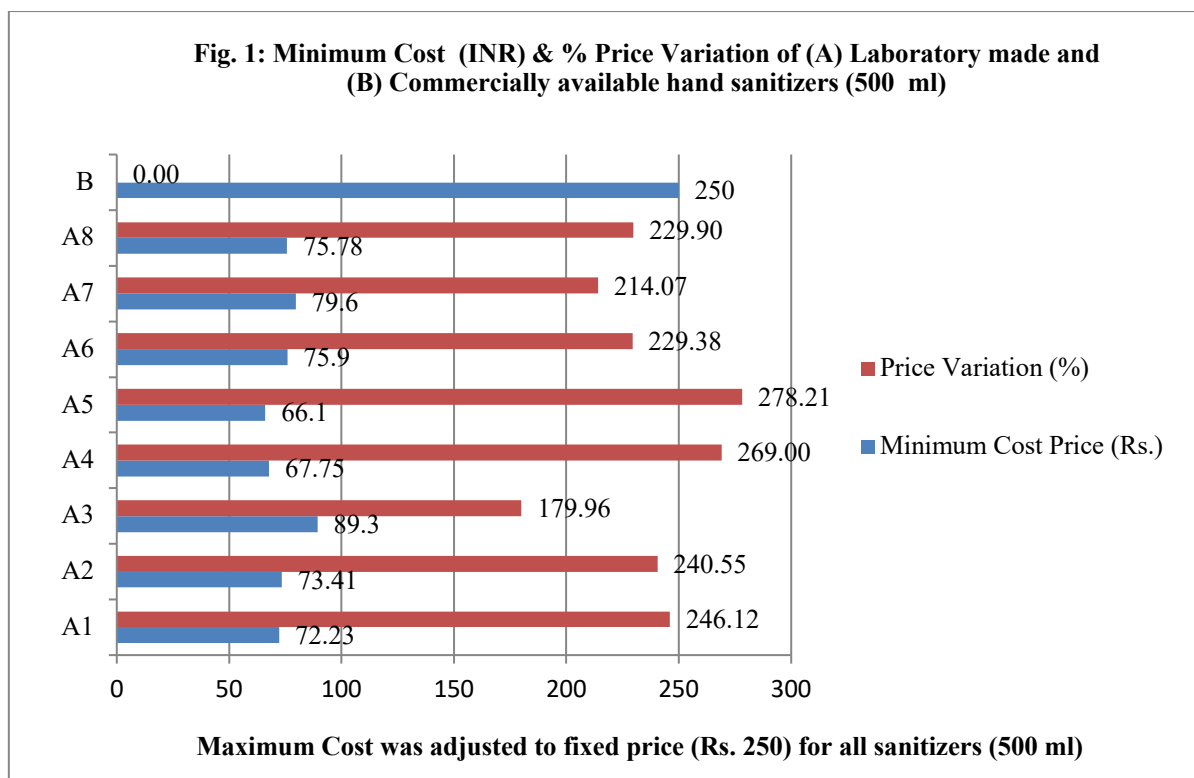


Figure 1: Minimum Cost (INR) & % Price Variation of (A) Laboratory made and (B) Commercially available hand sanitizers (500 ml)

Discussion

This study focused on the role of alcohol concentration needed for effective killing of germs and to prevent community transmission thereby. Isopropyl and ethyl alcohol are found to be very effective agents against microbial bacteria, fungi, and viruses between concentrations of 70% and 90%. Higher concentrations fail to produce a much more desirable effectiveness against microbes. Diluted alcohol with 10-40% deionized water makes alcohol based sanitizer an effective tool against pathogens including viruses. This adequate amount of water acts as a catalyst and has a significant role in denaturing the proteins of cell membranes of vegetative cells or protein based structures like viruses. Also, the presence of water slows down evaporation of alcohols and increases the surface contact time with the target membrane. The process of evaporation becomes instant, and protein coagulates at higher concentrations (>90% or above) rendering loss of its efficacy.[13]

In the viewpoint of this study, we illustrated the possible concentration variation as measured by alcoholometer in proper laboratory condition. Identities of purchased sanitizers were kept disclosed as our study needed only to focus on the fact that whether variation in concentration of alcohol based sanitizers of different resources would affect its therapeutic goal or not. Slight variation in alcohol concentration would not affect

its effectiveness in killing germs but concentration outside range of 60-95% would fail to justify its purpose of use. [14]

Also, transmission of viruses or other microbes through contact will boost the disease spread unknowingly to the community. Most of the laboratory made and branded sanitizers were found with negligible differences in mean concentration estimation. Here, insignificant p- value ≥ 0.05 indicated that observed concentrations were similar to our expected ones and as claimed by different brands of hand sanitizer available in the market (Table 1, Category A & B). But, this study found possible differences between observed and expected mean concentration. Since, most herbal and local hand sanitizers justified their alcohol concentration within effective ranges according to Centres for Disease Control and Prevention (CDC) and World Health Organization (WHO) guidelines but were compared to have slightly higher mean differences.

The p- values were observed ≤ 0.05 in many occasions while estimating alcohol concentrations in their various samples (Table 1, Category C & D). Overall, observed alcohol concentration merely altered than expected concentration in most of the laboratory based and commercial branded (mean diff. value in the range 0.33-1.33, $p < 0.05$) whereas most of the locally made sanitizer (mean diff. value in the range 0.5-6.17, $p > 0.05$) and herbal sanitizers

(mean diff. value in the range 0.33-4.67, $p > 0.05$) were shown with relatively more concentration variation. Cost effectiveness was achieved in commercially available hand sanitizers by applying alcohol at 70% concentration as permissible limit of alcohol concentration ranges between 70-90%. This is because concentration $> 90\%$ takes a greater time to act and doesn't kill as much bacteria as 70-90% alcohol. Therefore, 70% alcohol based formulations was established as both most cost and concentration effective preparation among various alcohol concentration based sanitizers.[11] Cost effectiveness can be explained by less amount of alcohol (70%) needed to prepare sanitizer which led to less expense during manufacturing process. The Government of India regulated the price of sanitizers by strictly limiting maximum selling or printed price as not exceeding Rs. 1.00/- per 2 ml volume for retail sanitizers irrespective of any composition, consistency or strength. [15]

Most of the commercial brands were authorized to serve for this purpose and they preferred making lowermost effective alcohol based sanitizers to attain the cheapest possible making cost. Therefore, all the brands of sanitizers in the market were found to have cost ratio 1:1 with no price variation. Price equalization despite of varying composition among various commercially available hand sanitizers led to possible demoralization of sanitizers manufacturing companies. This might create quality issues or provide ground to establish substandard companies to meet the huge demand of sanitizers in such pandemic viral disease outbreak. On the other hand, laboratory made sanitizers have higher cost variation. Highest cost variation was seen in A5 composition (Price variation=278.21%) with minimum cost price 66.10 (INR) followed by A4 (Price Variation=269%) with minimum cost price 67.75 (INR) whereas % cost variation was lowest in A3 (Price variation=179.96%) with highest value of minimum cost price 89.30 (INR) (Fig.1).

It can be suggested that isopropyl based liquid sanitizers were relatively cheaper than ethyl alcohol based sanitizers with higher percentage of price variation (Table 2). Though varying prices and larger cost differences among laboratory made sanitizers seemed more economic than purchased sanitizers, initiatives should be taken to lower the selling price to make it reach to poor socio-economic sections. Despite of all these measures, the lack of awareness and hygienic practices came out as major hindrances; thus, education and constant reinforcement about its benefits is also needed in Indian society. [16, 17] Improvisation in health infrastructure and facilities along with positive reinforcement for admissible use of sanitizers should be inevitably implemented to

combat such highly infectious diseases in future as well.

Conclusion:

Hand sanitizer was established as one of the most widely accepted effective tools to prevent COVID transmission globally until successful launching of vaccine against pathogenic noble corona virus. The present study concluded that proper concentration of alcohol used to make sanitizers must be established before final dispatch to ensure efficacy of the product despite a wide range of alcohol concentration known to be effective in killing harmful germs and viruses like corona virus. Variation in alcohol concentration though minor but needed to preclude likely malfunctioning of concerned manufacturers or any possible adulteration or misbranding of the sanitizers. Price valuation suggested that laboratory made sanitizers were more cheaper than individual ingredients estimated cost and no price change was noticed in commercial sanitizers as their prices were fixed and controlled by government in public interest.

Though, the Government of India strictly managed the price variations among different brands of sanitizers and fixed its maximum selling price based on volume but it would be prudent to bring down this cost to facilitate sanitizers to the poor and deprived sections. This would help to prevent severe community level transmission in the developing country like India where such disease might get flared up in uncontrolled fashion if reached to these sections.

Limitation of the study:

The study was performed in desired laboratory condition for estimation of alcohol concentration using alcoholometer at the temperature varying between 15-160c, which was minimum temperature acquired to carry out experimental tasks. Though alcoholometers were designed to give proper reading at 150c, slight discrepancy in reading might possibly prevail during concentration estimation. Also, the study has taken minimum cost of each ingredient along with fixed estimated packing cost to yield final minimum cost price of all laboratory made sanitizers. There might be negligible differences in estimating minimum possible prices of sanitizers on individual basis. But overall picture was under justification apart from these limitations of little worth.

Ethical approval: The study was approved by the Institutional Ethics Committee (Vide letter No.-NMCH/IEC/2022/28). All procedures contributing to this study have been conducted complying with the institutional ethical guidelines.

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