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Original Article

Anaesthesia Section

Intravenous Propofol and Inhalational Sevoflurane for Ease of Classic Laryngeal Mask Airway Insertion in Patients Undergoing Elective Surgery: A Randomised Clinical Trial

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ABSTRACT

Introduction: The Laryngeal Mask Airway (LMA) has gained extensive popularity for airway management during surgery. Propofol, the most commonly used induction agent for LMA insertion, causes significant haemodynamic changes. Sevoflurane has the potential to be as good an induction agent as propofol.

Aim: To compare ease of insertion of classic LMA in patients undergoing elective surgery using intravenous propofol and inhalational sevoflurane.

Materials and Methods: The study was a randomised clinical trial conducted in the Operation Theatres of Midnapur Medical College and Hospital, Medinipur, West Bengal, India, from August 2019 to July 2020. Eighty patients of American Society of Anaesthesiologists (ASA) physical status grade I and II, of both sexes, and aged between 18 years to 65 years were equally divided into two groups: group P (Propofol group) and group S (Sevoflurane group). Group P was given injection Propofol 2.5 mg/kg body weight and group S was given vital capacity breath induction with 8% sevoflurane and oxygen at 8 litres/min. Loss of Consciousness (LOC) was confirmed and induction time was noted for each group. After confirmation of ease of mouth opening, by an independent observer, LMA insertion was attempted. Ease of LMA insertion was assessed by a predefined 18 points table along with time to LMA insertion and number of attempts. Haemodynamic changes and adverse effects were also recorded. Chi-square test or Student's t-test were used and a p-value ≤0.05 was considered as statistically significant.

Results: With respect to age, sex and weight there were no significant differences between the two groups. Induction time was significantly less in group P (51.85±6.66 seconds) compared to group S (68.38±13.93 seconds) (p-value=0.0001), but LMA insertion time, number of attempts and overall ease of LMA insertion conditions according to the 18 points score were comparable between the two groups. Mean arterial pressure at certain points after induction was significantly less in group P (at 3 minute p-value=0.009 and at 5 minute p-value=0.007). Apnea was significantly more in group P (p-value=0.023).

Conclusion: Sevoflurane was comparable to propofol for LMA insertion in respect of ease of insertion and insertion time. Although induction time was significantly less for propofol, sevoflurane offered better haemodynamic stability and lesser incidence of apnea.

Keywords: Airway management, Apnea, Induction agent, Vital capacity breath

INTRODUCTION

The Laryngeal Mask Airway (LMA) has become a valuable and important device for the airway management in anaesthesia practice [1]. LMA is a supraglottic airway device that is designed to provide and maintain a seal around the laryngeal inlet for spontaneous ventilation and permits positive pressure ventilation at pressures upto 20 cm H_2O [2]. It provides a better airway with respect to ventilation and oxygenation than a conventional face mask and oropharyngeal airway and without need for muscle relaxation and laryngoscopy, thus minimising haemodynamic fluctuations [3].

Propofol is the most commonly used induction agent for LMA insertion, although it is not ideal [4]. Induction with propofol is faster but associated with several adverse effects including hypotension, pain on injection, apnea, and excitatory patient movement. Sevoflurane is a non pungent, non irritating, inhaled anaesthetic associated with smooth induction and recovery, without significant haemodynamic changes and period of apnea. It has the potential to be the best inhalational induction agent for LMA insertion [5].

A study reported that LMA insertion and jaw relaxation time was prolonged for sevoflurane in comparison to propofol, more with Tidal Volume Breathing (TVB) method as compared to vital capacity breathing method of inhalational induction [6]. Although in many studies [4,7,8] LMA insertion with sevoflurane using the vital capacity induction breathing was slower than intravenous propofol, in few studies [9,10], however, induction with sevoflurane took lesser time compared to propofol.

Bain's and closed circuits were employed in majority of the studies, while utilisation of Magill's circuit, most physiological method of spontaneous induction, was rare [7]. Use of Classic LMA, although being widely available and cheaper, was reported in a sole study [11]. Thus, with the background of conflicting evidences regarding induction time between the two agents, the current study was undertaken using Classic LMA and Magill's circuit, best suited for spontaneous ventilation.

The primary objective of this randomised study was comparison of ease of insertion characteristics of classic LMA in patients undergoing elective surgery using intravenous propofol and inhalational sevoflurane. While time to induction and LMA insertion along with number of attempts, monitoring haemodynamic changes and incidence of complications were the secondary objectives.

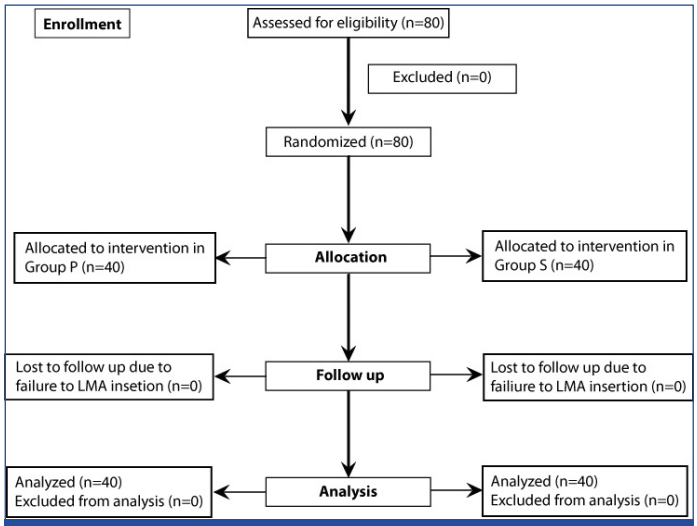
MATERIALS AND METHODS

The study was a randomised clinical trial conducted in the Operation Theatres of Midnapur Medical College and Hospital, Medinipur, West Bengal, India, from August 2019 to July 2020. After obtaining Institutional Ethics Committee clearance (No:MMC/IEC-2019/193) and successful registration in Clinical trials registry of India (CTRI/2019/07/020357).

Inclusion and Exclusion criteria: Eighty American Society of Anaesthesiologists (ASA) grade I and II patients of either sex, aged

between 18-65 years, weight between 30 to 70 kg admitted for undergoing elective surgeries of less than one hour duration were included in the study. However, heavy smokers, patients with upper respiratory tract infection, presenting for oral and emergency surgeries and allergic to induction drugs were excluded from the study.

The stepwise procedural CONSORT diagram is depicted in [Table/Fig-1].



[Table/Fig-1]: Procedural CONSORT flow diagram.

Sample size calculation: Based on an earlier study [4], in order to achieve a clinically relevant difference (mean difference) in LMA insertion time between propofol and sevoflurane groups with power of study as 80% and 95% confidence interval (alpha=0.05) a sample size of 80 patients were chosen for the study and equally divided in two groups P and S of 40 patients each.

Procedure

After pre-anaesthetic check-up, patients enrolled for the study were given tablet alprazolam 0.5 mg night before surgery and were kept nil per oral for 8 hours. The patients were randomly allocated into two groups, group P {propofol Intravenous (IV) induction} and group S {Vital Capacity Breath (VCB) sevoflurane induction} of 40 patients each, by computer generated random assignment.

Premedication with injection ondansetron 4 mg i.v., injection glycopyrrolate 0.2 mg i.v. and injection fentanyl 2 mcg/kg i.v. was given to all patients. The injection site was obscured and a scented face mask was used to mask the smell of sevoflurane in order to ensure proper patient blinding. Preoxygenation with 100% Oxygen at the rate 8L/min using Magill circuit (mapleson A) with 2L reservoir bag was done for 3 minutes in both groups.

Group S patients were preoxygenated using one anaesthesia machine, while a Magill circuit primed with 8% sevoflurane in oxygen at rate 8 litres/min for 30 seconds in a second machine was used for induction. Patients were asked to inhale sevoflurane by vital capacity breath induction method as explained to them earlier. Loss of Consciousness (LOC) was confirmed by checking eyelash reflex for both groups. Ease of mouth opening was assessed by an independent observer and if unsuccessful in first attempt, patients were allowed to continue spontaneous/assisted ventilation on sevoflurane 8% in 8 litres of oxygen and further attempts were made every 30 seconds upto a maximum of four times.

Group P was given injection propofol 2.5 mg/kg body weight intravenous at the rate 40 mg/10seconds. The point start of injection of propofol or introduction of sevoflurane 8% was considered as the starting point of induction. Jaw relaxation was assessed and if not adequate, Propofol boluses of 0.5 mg/kg i.v. was given every 30 seconds and repeated upto a maximum of four attempts.

The LMA was inserted when jaw relaxation was adequate, by an experienced anaesthesiologist, in both groups of patients who was outside the room and called in at the time of insertion. Before his entry the vaporiser or the i.v. cannula site was covered, however with the smell of sevoflurane and two anaesthesia machines used in the same room for group S, blinding the anaesthesiologist was not completely possible. Hence, this study was single blinded. An independent observer present inside the operation room recorded the various study parameters like induction time, LMA insertion time, number of attempts and over all conditions of ease of LMA insertion based on parameters as given in [Table/Fig-2] [7]. The classical method described by Dr. Archie IJ Brain was used for LMA insertion [12]. After insertion of LMA, position was checked and adequate ventilation was be confirmed by End Tidal Carbon Dioxide ($EtCO_2$) and auscultation.

Variables	Score		
	3	2	1
Jaw relaxation	Full	Partial	Nil
Ease of Insertion	Easy	Difficult	Impossible
Gagging	Nil	Minor	Severe
Coughing	Nil	Minor	Severe
Laryngospasm	Nil	Partial	Total
Head and limb movements	Nil	Moderate	Vigorous
Total score: Excellent=18; Satisfactory=16-17; Poor=less than 16			

[Table/Fig-2]: LMA insertion Characteristics [7].

Any failures of insertion of LMA after four attempts, was to be rescued with injection succinylcholine 1 mg/kg body weight i.v. followed by endotracheal tube intubation or LMA insertion whichever was feasible. Anaesthesia was continued in both groups by giving sevoflurane 4.0% in 67% nitrous oxide in oxygen at a fresh gas flow rate of 8 L/min with a change in the circuit to Bain's circuit for next 3 minutes, before decreasing the dial concentration of sevoflurane to 2% for maintenance. No controlled or assisted breaths were be given unless the patient suffered oxygen desaturation to a pulse oximetry reading of <90%. The decision not to manually ventilate our patients between LMA insertion attempts was intended to avoid abolishing their hypercarbic drive, which would prolong the period of apnea.

Haemodynamic parameters like Heart Rate (HR), Mean Arterial Pressure (MAP), Oxygen Saturation (SpO_2) and End Tidal Carbon Dioxide ($EtCO_2$) were monitored and recorded from the beginning of induction upto 10 minutes at specified intervals.

Complications, if any like involuntary movement (head and limb movements), coughing, gagging, apnea and laryngospasm were noted. At the end of the operation, the LMAs were removed and checked for presence of blood on them. Once fully awake, the patients were interviewed whether they had a sore throat or not.

STATISTICAL ANALYSIS

Collected data were entered into Microsoft Excel (version 10.0). Quantitative data were presented as mean and Standard Deviation (SD). Student t-test was applied to compare the data in the two groups. Qualitative data was presented with as percentage table. Chi-square test was used to find association. Statistical Package for the Social Science Software (SPSS) version 27.0 (SPSS Inc. Chicago, IL, USA) and Graph Pad Prism version 5 were used for analysis. A p-value<0.05 was considered statistically significant.

RESULTS

With respect to age, sex and weight there were no significant differences between the two groups [Table/Fig-3].

Induction time was significantly rapid with i.v. propofol (51.85±6.66 seconds) than with sevoflurane (68.38±13.93 seconds), (p-value= 0.0001). Mean time for LMA insertion (78.30±12.21 sec) was lesser in group P compared to group S (84.53±18.72 seconds), but not significant (p-value=0.0821). Number of attempts for LMA insertion

Characteristics		Group P (n=40)	Group S (n=40)	p-value (Unpaired student's t-test, Chi-square test)
Age (years) Mean±SD		36.48±12.36	36.30±12.67	0.9503
Weight (kg) Mean±SD		55.78±8.78	56.38±9.04	0.7641
Sex distribution	Male	20 (50%)	21(52.5%)	0.8230
	Female	20 (50%)	19 (47.5%)	

[Table/Fig-3]: Demographic data of both the groups.
p-value <0.05 was considered statistically significant; (Unpaired Student's t-test, Chi-square test); n=40 in each groups

were comparable in both the groups; p-value=0.5158 [Table/Fig-4]. There was no significant difference between two groups regarding jaw relaxation (p-value=0.6968) and ease of LMA insertion (p-value=0.6968).

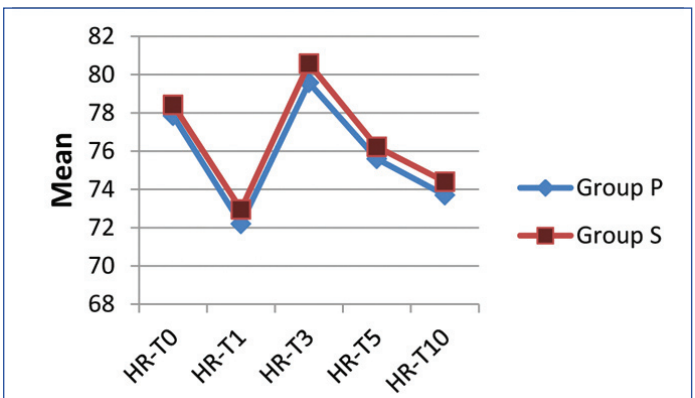
Characteristics	Group P (n=40)	Group S (n=40)	p-value (Unpaired student's t-test)
Induction time (sec)	51.85±6.66	68.38±13.93	0.0001*
LMA insertion time (sec)	78.30±12.21	84.53±18.72	0.0821
Number of attempts	1.07±0.27	1.13±0.40	0.5158

[Table/Fig-4]: Induction time and Laryngeal Mask Airway (LMA) insertion data.
Values are mean±SD; *significant; p-value <0.05 was considered statistically significant

Overall conditions of LMA insertion according to scoring system in [Table/Fig-2] were comparable as depicted in [Table/Fig-5]. Baseline haemodynamic parameters were comparable in both the groups. Mean HR increased after insertion of LMA but was statistically insignificant [Table/Fig-6]. Mean MAP became significantly low in group P at 3 minutes (p-value=0.0099) and 5 minutes (p-value= 0.0075) after induction as compared with group S [Table/Fig-7]. There were no significant differences between the groups in terms of mean SpO_2 [Table/Fig-8] and mean $EtCO_2$ [Table/Fig-9] at the specified time intervals.

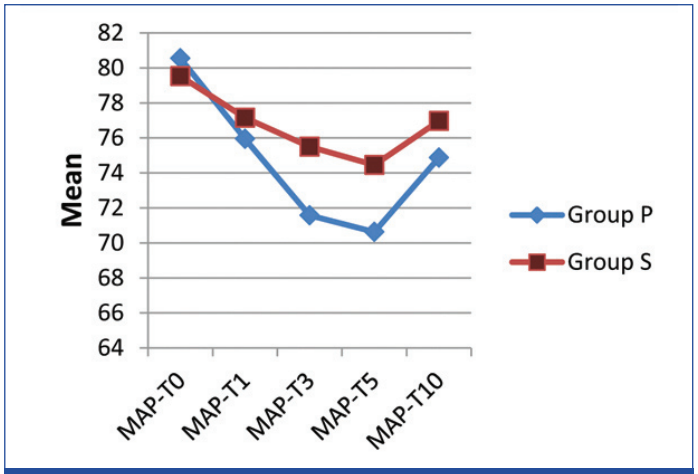
Characteristics	Mean scores ±SD		p-value (Chi-square test)
	Group P (n=40)	Group S (n=40)	
Jaw relaxation	2.93±0.27	2.90±0.30	0.6968
Ease of LMA insertion	2.93±0.27	2.90±0.30	0.6968
Coughing	2.93±0.27	2.95±0.22	0.6492
Gagging	2.98±0.16	2.98±0.16	1
Head limb movement	2.95±0.22	2.95±0.22	1
Laryngospasm	3.00±0	3.00±0	Not applicable
Total score	17.70±0.65	17.68±0.66	0.8643

[Table/Fig-5]: Overall conditions of LMA insertion.
p-value <0.05 was considered statistically significant; LMA: Laryngeal mask airway

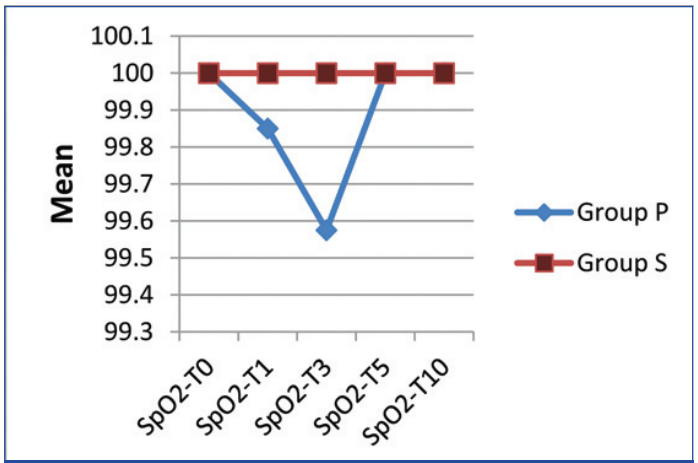


[Table/Fig-6]: Mean HR at specified intervals.
HR: Heart rate

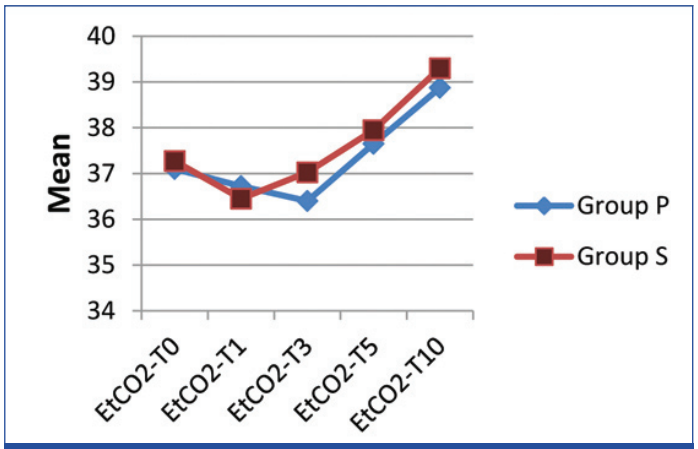
Complications were comparable in both the groups except incidences of apnea were significantly high in group P than group S (p-value=0.023). No incidence of laryngospasm, sore throat and blood on LMA were recorded [Table/Fig-10].



[Table/Fig-7]: Mean MAP at specified intervals.
MAP: Mean arterial pressure



[Table/Fig-8]: Mean SpO_2 at specified intervals.
SpO_2: Oxygen saturation



[Table/Fig-9]: Mean $EtCO_2$ at specified intervals.
$EtCO_2$: End tidal carbon dioxide

Characteristics	Group P (n=40)	Group S (n=40)	p-value (Chi-square test)
Coughing	3	2	0.6492
Gagging	1	1	1
Head limb movement	2	2	1
Apnea	9	2	0.0230*

[Table/Fig-10]: Complications.
*p-value <0.05 was considered statistically significant

DISCUSSION

For Laryngeal Mask Airway (LMA) insertion propofol is undoubtedly the best induction agent, however with quite a few adverse effects. Inhalational induction agents like sevoflurane have the potential to be a safer alternative and have been shown to be even better induction

agent compared to propofol in few studies [10,13]. Intravenous propofol and inhalational sevoflurane have been compared in a number of studies for ease of insertion of LMA [4]. In most of the studies, with few exceptions [14], Bain's circuit [11] or circle system [4] was used though neither was ideal for spontaneous ventilation. In comparison to tidal volume method [11] of sevoflourane induction vital capacity breath method [14], being more quicker, with good patient acceptance and haemodynamic stability [15] was employed in most studies, although still significantly slower than propofol [14]. Sarkar M et al., and Sivalingam P et al., showed that induction was even faster with sevoflourane and LMA insertion time comparable to propofol, unlike majority of studies [9,10]. Administration of an opioid like fentanyl prior to LMA insertion produces synergistic effect with both propofol and sevoflurane [16].

Hence, this prospective randomised control trial was conducted on adult population of both sexes, in short duration elective surgeries, using i.v. propofol and VCB sevoflurane with Magill circuit for comparison of induction and insertion characteristics of Clinical Laboratory Management Association (CLMA) haemodynamic stability and incidence of complications. Mean induction time with sevoflurane by TVB in studies by Gupta Y et al., was (145.93±53.07 sec) and Kati I et al., (120±30 sec) [11,17]. VCB method of induction with sevoflurane was used in this study with mean time of (68.38±13.93 sec), which was definitely faster than TVB induction but significantly slower than mean induction time of (51.85±6.66 sec) in propofol group.

In this study, mean LMA insertion time was faster in group P than group S although statistically insignificant (p-value=0.082). Similar findings were shown by Prakash S and Sreedevi J and Sarkar M et al., [8,9]. In both of these studies, similar to our study, a dose of 2.5 mg/kg propofol was used and VCB induction with sevoflurane was carried out. Siddik-Sayyed SM et al., had shown significantly faster LMA insertion time with propofol induction [5]. They had used much higher dose of propofol (3 mg/kg).

In our study LMA insertion was successful in all patients and mean number of attempts were comparable in both the groups (p-value=0.515). In their studies, Prakash S and Sreedevi J and Dharmalingam AL et al., also had shown similar results [8,18]. Unlike our study, the number of attempts was much more in sevoflurane group in the study of Ti LK et al., which could be due to administration of lignocaine with propofol group only and no use of opioids [4].

During LMA insertion both the groups were compared based on the criteria of conditions for insertion (jaw opening, ease of insertion) and complications (coughing, gagging, laryngospasm, head limb movement), and scored on a scale from 1 to 3 similar to study by Priya V et al., and Prakash S and Sreedevi J [7,8]. In the study by Priya V et al., 28% in the propofol group and 56% in the sevoflurane group had partial jaw opening, whereas in our study jaw relaxation was almost equally excellent in both groups in majority of patients (90% in group S and 92.5% in group P) [7], quite similar to findings of Prakash S and Sreedevi J and Udaybhaskar V et al., [8,19]. Ease of insertion, in our study was equally excellent in 95% of group P patients and 92.5% group S patients (p-value=0.6968) and comparable with the findings of Prakash S and Sreedevi J and Udaybhaskar V et al., [8,19]. The incidence of coughing was 7.5% in propofol group while 5% in sevoflourane group, but none were statistically significant. Sivalingam P et al., reported coughing in 12% in the propofol group and 20% in the sevoflurane group [10], while incidence was nil in study by Prakash S and Sreedevi J [8]. There was no incidence of life-threatening laryngospasm in either group similar to Prakash S and Sreedevi J [8], but contrary to findings of Siddik-Sayyed SM et al., and Priya V et al., where incidence was respectively 8% and 12% in sevofourane group [5,7]. Thus, in our study, over all condition of LMA insertion were comparable between the two groups (p-value=0.8643), similar to the study of Prakash S and Sreedevi J but different from the findings of Priya V et al., where over all condition in Propofol group were significantly favourable [7,8].

Mean of MAP was significantly low at 3 minute (p-value=0.0099) and 5 minute (p-value=0.0075) after induction with propofol in comparison with sevoflurane in our study. There was increase in HR in both groups after insertion of LMA in both the groups but it was statistically insignificant. Significant changes in mean MAP with propofol were also recorded by Prakash S and Sreedevi J and Dharmalingam AL et al., [8,18], while in their studies Sarkar M et al., and Patel AB et al., found haemodynamic changes were insignificant [9,20].

Incidence of apnea was significantly high with propofol group as compared to sevoflurane group (p-value=0.023) in our study. Similar findings were seen in studies by Siddik-Sayyed SM et al., and Gupta Y et al., [5,11]. Other complications like sore throat and blood in the LMA were absent in our study like Prakash S and Sreedevi J [8].

Limitation(s)

Limitation of this study was difficulty in comparing the equivalent dose of intravenous and inhalational agents. Depth of anaesthesia and cost of anaesthesia comparison between sevoflurane and propofol could not be accomplished and complete blinding of the LMA inserting anaesthesiologist was not technically possible.

CONCLUSION(S)

Sevoflurane was comparable to Propofol for LMA insertion in respect of ease and time of insertion. Although induction time was significantly less for propofol, sevoflurane offered better haemodynamic stability with less incidence of apnea. Randomised double blinded trials on comparison of LMA insertion conditions for propofol and sevoflurane using different varieties of LMA or other supraglottic devices may be undertaken in the future to enrich our knowledge.

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- Manual Googling: Jun 14, 2021
- iThenticate Software: Jul 30, 2021 (11%)

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