https://doi.org/10.29309/TPMJ/2023.30.04.7389

The Professional Medical Journal
www.theprofesional.com
2023, Volume, 30 Issue, 04

ORIGINAL ARTICLE

Hemostatic and hemodynamic effects of two different doses of epinephrine during endoscopic sinus surgery: A randomized controlled trial.

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Article Citation: Mujahid AM, Saleem MW, Ali S, Wahab MU, Shakoor A, Saad AB. Hemostatic and hemodynamic effects of two different doses of epinephrine during endoscopic sinus surgery: A randomized controlled trial. Professional Med J 2023; 30(04):516-522. https://doi.org/10.29309/TPMJ/2023.30.04.7389

ABSTRACT… Objective: To determine the hemostatic and hemodynamic effects of two different doses of epinephrine during endoscopic sinus surgery. **Study Design:** Randomized Control Trial. **Setting:** Department of Otolaryngology, Teaching Hospital, D. G. Khan Medical College, Dera Ghazi Khan. **Period:** 1st January, 2020 to 31st December, 2020. **Material & Methods:** A randomized control trail was done at ENT Department, Teaching Hospital Dera Ghazi Khan. 96 subjects were included and divided into two groups. Group-A patients received lidocaine hydrochloride, 2%, with 1:100,000 epinephrine while group-B patients received lidocaine, 2%, with 1:200,000 epinephrine. Data were collected through a structured proforma and analyzed using SPSS version 22.0. Numerical variables presented as mean and standard deviation and qualitative variables as frequency and percentages were calculated. Independent sample t test was used to compare the quantitative variables between both groups. Chi-square test was used to estimate the association between qualitative variables. P-value <0.05 was considered significant. **Results:** Among 30 patients of Group-A, 60.4% were males, mean age was 39.73 ± 10.736 years and the mean blood loss was 202.58 ± 12.218 ml. In Group-B, 64.6% were males, mean age was 39.35 ± 11.421 years and the mean blood loss was 176.90 ± 5.846 ml. In Group-A, mean heart rate at 0 minute, and 5 minutes was 76.54 ± 1.786, and 76.65 ± 1.296 while in Group-B was 75.50 ± 2.568, and 73.88 ± 1.886, respectively. In Group-A, mean SBP at 0, and 5 minutes was 108.17 ± 3.191, and 107.17 ± 2.234 while in Group-B was 106.25 ± 3.795, and 103.56 ± 1.821, respectively. **Conclusion:** Lidocaine hydrochloride 2% with epinephrine dose of 1:200,000 is more effective during endoscopic sinus surgery than epinephrine dose of 1:100,000 with Lidocaine hydrochloride 2%.

Key words: Endoscopic Sinus Surgery, Doses, Hemostatic Effect, Hemodynamic Effect, Lidocaine with Epinephrine.

INTRODUCTION

Chronic rhinosinusitis is an important health dilemma that affects 5-12 percent of general population.[1] It can be associated with or without nasal polyps. Presence of >2 indications leads to persistent rhinosinusitis and these indications may include nasal congestion or nasal discharge, loss or decrease in smell for 12 weeks or more or facial pressure/pain. Allergic indication such as watery rhinorrhea, itchy watery eyes, sneezing and nasal itching are considered as well.[2] Patients with chronic rhinosinusitis manage their indications initially by medical treatment such as antibiotics, corticosteroids and nasal saline irrigation.[3] These therapies show varying degree of effectiveness because of diversity of the disease. For those patients who cannot be cured with medical treatment, surgical intervention is offered to reduce the signs and symptoms.[4]

The surgical approach for medically resistant cases is via endoscopic sinus surgical treatment (ESS).[5] It is an extensively utilized surgical procedure for the treatment of several sinus pathologies.[6] It is fast, tolerable and minimally invasive technique.[7] It ranges from the basic and comparatively straightforward techniques to advanced surgical treatment such as endoscopic dacryocystorhinostomy, orbital nerve decompression and endo nasal skull base techniques. The benefits of ESS include no external scars, less damage to surrounding

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Article received on: 15/12/2022
Accepted for publication: 17/02/2023

tissue, short hospital stays and early recovery.[8]

Endoscopic Sinus Surgery technique is mostly related to acute stress responses leading to significant hemodynamic modification such as changes in heart rate, blood pressure and rhythm. During ESS, the bleeding is a major concern and a great challenge for the surgeons as well as anesthesiologists.[9] Intraoperative blood loss during ESS poses an extra dimension to an already scientifically demanding surgical technique due to narrow sino nasal surgical field and endoscopic instruments utilization.[10] During surgical treatment, controlled hypotension is progressively significant method and systolic blood pressure is decreased to 80-90mmHg while mean arterial pressure is decreased to 50-65mmHg (30 percent reduction in the baseline mean arterial pressure). This method reduces blood loss as well as improves surgical field.[11]

Vasopressors are being used since a long time as hemostatic agents in nasal surgical treatment. Drugs such as epinephrine, norepinephrine, phenylephrine, oxymetazoline and vasopressin analogues are presently utilized as adjuvants along with local anesthetics for the preparation of nasal passages prior to nasal surgical treatment. The epinephrine works like a vasoconstrictor of the capillaries and is believed as vasoconstrictor of the choice along with local anesthetics. Also the epinephrine averts the toxicity by decreasing local anesthetics systemic absorption from nasal mucosa as well as prolonging the time of action in addition to nerve block intensity generated through local anesthetics.[12] It triggers the α- and β-adrenoceptors and its hemodynamic effects are dose dependent. For hemostasis, epinephrine is extensively utilized during ESS carried out under general and local anesthesia.[13] Infiltration of local anesthetic agent (lignocaine) with epinephrine is commonly utilized to boost hemostasis, reduce blood loss, optimize visualization of surgical landmarks by reducing mucosal blood flow and also relieve pain.[14] Along with benefits some unfavorable effects can occur that include tachycardia, arrhythmias, hypotension and hypertension. During sinus surgical treatment concentrated (1:1000) topical epinephrine is utilized to control the blood loss. Further diluted epinephrine (1:100,000 / 1:200,000), mixed with anesthetic agent (2% lidocaine), is mostly injected during the nasal cavity and sinus surgery to promote analgesia and to provide hemostasis.[15]

There is no local study available regarding the use of epinephrine. Hence this study was carried out to evaluate the hemostatic and hemodynamic effects of two different doses of epinephrine during endoscopic sinus surgery. This study will help the use of epinephrine with lidocaine for endoscopic surgery of different regions as well as endoscopic sinus surgery.

Objectives

To determine the hemostatic and hemodynamic effects of two different doses of epinephrine during endoscopic sinus surgery.

MATERIAL & METHODS

A Prospective Randomized Controlled Trial was conducted at Otolaryngology (ENT) Department, Teaching Hospital, D. G. Khan Medical College from 1st January 2020 to 31st December, 2020. Total 96 patients visiting the ENT department were enrolled and were divided into two groups (48 in each). Group-A patients received lidocaine hydrochloride, 2%, with 1:100,000 epinephrine while group-B patients received lidocaine, 2%, with 1:200,000 epinephrine. Simple stratified randomization sampling technique was used to enroll participants using random number table with 1:1 allocation ratio for each group.

Patients of either gender with age 18 to 60 years and patients with chronic sinusitis and sinonasal polyposis were included. Patients with history of bleeding disorders, hypertension, ischemic heart diseases and Diabetes Mellitus were excluded from study. After the approval from ethical review committee, written informed consent was obtained (136340/Teach: Hosp). Surgery was performed under General Anesthesia in all the cases. After the proper positioning of patient, endoscope was used to examine the bilateral nasal cavities for normal anatomical structures and for extension of the disease. Baseline heart rate and blood pressure were recorded in all patients. Before

procedure local anesthesia was injected with either 2% lidocaine with 1: 100,000 epinephrine (Group A) or either 2% lidocaine with 1: 200'000 epinephrine (Group B) using syringe into the nasal septum , middle turbinate, axilla of middle turbinate, and inferior turbinate. Approximately four ml solution was injected bilaterally. In- and out-fracture of the inferior turbinate were performed to improve access to the uncinate process and middle meatus. The turbinate was then lateralized under direct vision, starting posteriorly and moving anteriorly and gently elevates the uncinate anteriorly. Uncinectomy was performed with a sickle knife or freer dissector, next we did middle meatal antrostomy and widen the natural maxillary osteum clear the disease and ethmoidectomy was done to clear the disease with widened the natural osteum same is done with sphenoid and Frontal sinuses drainage and for disease clearance. Bleeding, heart rate and blood pressure were monitored in both groups and nasal packing was done for hemostasis and removed next post-operative day blood.

These parameters were monitored throughout the procedure by concerned consultant anesthetist and repeated for 5 minutes with interval of one minutes. The demographic data of patients, presence of nasal polyps and extent of surgery were recorded for further analysis. Amount of blood loss was assessed at the end of each surgery using the validated scale. The collected data was entered and analyzed using SPSS version 22.0. Mean and standard deviation were calculated for quantitative variables and frequency and percentages for qualitative variables. Independent t test was used to compare the quantitative variables between both groups. Chi-square test was used to estimate the association between qualitative variables. P-value <0.05 was considered significant.

RESULTS

Among 48 patients of Group-A (1:100,000), 13 (27.1%) were <30 years old, 9 (18.7%) were 31-40 years old, 18 (37.5%) were 41-50 years old and 8(16.7%) patients were 51-60 years old. The mean age of the patients was 39.73±10.736 years. Among 48 patients of Group-B (1:200,000), 12 (25.0%) were <30 years old, 15(31.3%) were 31-40 years old, 12 (25.0%) were 41-50 years old and 9 (18.7%) patients were 51-60 years old. The mean age of the patients was 39.35±11.421 years. Table demonstrates that among 48 patients of Group-A, 29 (60.4%) were male and 19(39.6%) were female. Likewise among 48 patients of Group-B, 31 (64.6%) were male and 17 (35.4%) were female. 26 (54.2%) had blood loss <200ml while 22 (45.8%) had blood loss >200 ml. The mean blood loss was 202.58±12.218 ml. Among 48 patients of Group-B, all (100.0%) had blood loss <200ml. The mean blood loss was 176.90+5.846 ml. (Table-I).

All (100.0%) patients in both groups had normal heart rate (<100 bpm) at zero, one, two, three, four and five minutes. In Group-A, mean heart rate at 0, 1, 2, 3 , 4 and 5 minutes was 76.54±1.786, 82.52±3.313, 81.50±2.798, 79.08±1.471, 77.85±1.220 and 76.65±1.296, respectively. In Group-B, mean heart rate at 0, 1, 2, 3, 4 and 5 minutes was 75.50±2.568, 77.60±2.394, 76.56±2.230, 75.731.976, 74.83±1.894 and 73.88±1.886, respectively. (Table-II).

Group-A, 48(100.0%), 19(39.6%), 0(0.0%), 34 (70.8%), 48(100.0%) and 48(100.0%) had normal SBP (<120 mmHg) while remaining proportion had SBP >120 mmHg at 0, 1, 2, 3, 4 and 5 minutes, respectively. However, in Group-B all (100.0%) had normal SBP (<120 mmHg) at 0, 1, 2, 3, 4 and 5 minutes, respectively. Table asserts that in Group-A patients mean SBP at 0, 1 min, 2 min, 3 min, 4 min and 5 minutes was 108.17±3.191, 122.58±5.111, 128.67±4.329, 117.54±2.932, 111.29±2.315 and 107.17±2.234, respectively. In Group-B patients, mean SBP at 0 min, 1 min, 2 min, 3 min, 4 min and 5 minutes was 106.25±3.795, 110.00±3.262, 108.58±2.457, 106.69±1.937, 105.19±1.830 and 103.56±1.821, respectively. (Table-III). Group-A patients, mean DBP at 0, 1, 2, 3, 4 and 5 minutes was 63.23±3.191, 73.17±3.131, 74.38±4.928, 68.15±3.696, 64.00±3.080 and 60.27±2.403, respectively. In Group-B patients, mean DBP at 0, 1, 2, 3, 4 and 5 minutes was 62.48±3.753, 65.62±4.190, 64.17±3.663, 62.17±3.442, 60.71±3.326 and 58.79±3.307, respectively. (Table-IV). Above

table demonstrates that among 48 patients of Group-A, 5(10.4%), 23(47.9%), 17(35.4%), 2(4.2%) and 1(2.1%) patient had Grade-1, -2, -3, -4 and -5 surgical field, respectively. The mean surgical field was 2.40±0.818. Among 48 patients of Group-B, 7(14.6%), 27(56.2%), 12(25.0%) and 2(4.2%) patients had Grade-1, -2, -3, and -4 surgical field, respectively. The mean surgical field was 2.19±0.734. (Table-V).

Variables (n=96)		Group-A (1:100,000) Frequency (%)	Group-B (1:200,000) Frequency (%)	P- Value
Age	<30 years	13 (27.1%)	12 (25.0%)	0.700
	31-60 years	35 (72.9%)	36 (75.0%)	
Gender	Male	29 (60.4%)	31 (64.6%)	0.673
	Female	19 (39.6%)	17 (35.4%)	
Blood Loss	<200 ml	26 (54.2%)	48 (100.0%)	0.000
	>200 ml	22 (45.8%)	0 (0.0%)	

Table-I. Demographic variable among subjects

HR (n=96)	Group-A (1:100,000) Mean±SD	Group-B (1:200,000) Mean± SD	P-Value
0 minute	76.54 ±1.786	75.50±2.568	0.217
1 minute	82.52± 3.313	77.60±2.394	0.000
2 minutes	81.50±2.798	76.56±2.230	0.000
3 minutes	79.08±1.471	75.73±1.976	0.000
4 minutes	77.85±1.220	74.83±1.894	0.000
5 minutes	76.65±1.296	73.88±1.886	0.000

Table-II. Comparison of mean heart rate in both groups

SBP (n=96)	Group-A (1:100,000) Mean±SD	Group-B (1:200,000) Mean±SD	P-Value
0 minute	108.17±3.191	106.25±3.795	0.159
1 minute	122.58±5.111	110.00±3.262	0.000
2 minutes	128.67±4.329	108.58±2.457	0.000
3 minutes	117.54±2.932	106.69±1.937	0.000
4 minutes	111.29±2.315	105.19±1.830	0.000
5 minutes	107.17±2.234	103.56±1.821	0.000

Table-III. Comparison of mean systolic blood pressure in both groups

DBP (n=96)	Group-A (1:100,000) Mean±SD	Group-B (1:200,000) Mean±SD	P-Value
0 minute	63.23±3.191	62.48±3.753	0.596
1 minute	73.17±3.131	65.62±4.190	0.00
2 minutes	74.38±4.928	64.17±3.663	0.00
3 minutes	68.15±3.696	62.17±3.442	0.00
4 minutes	64.00±3.080	60.71±3.326	0.00
5 minutes	60.27±2.403	58.79±3.307	0.11

Table-IV. Comparison of mean diastolic blood pressure in both groups

Surgical Field	Group-A (1:100,000) Frequency (%)	Group-B (1:200,000) Frequency (%)	P-Value
Grade 1	5 (10.4%)	7 (14.6%)	0.642
Grade 2	23 (47.9%)	27 (56.2%)	
Grade 3	17 (35.4%)	12 (25.0%)	
Grade 4	2 (4.2%)	2 (4.2%)	
Grade 5	1 (2.1%)	0 (0.0%)	

Table-V. Comparison of surgical field in both groups

P-value = 0.642

0 = No bleeding (cadaveric conditions)

1 = Slight bleeding, no suctioning required

2 = Slight bleeding, occasional suctioning required

3 = Slight bleeding, frequent suctioning required; bleeding threatens surgical field a few seconds after suction is removed

4 = Moderate bleeding, frequent suctioning required, and bleeding threatens surgical field directly after suction is removed

5 = Severe bleeding, constant suctioning required; bleeding appears faster than can be removed by suction; surgical field severely threatened and surgery usually not possible

DISCUSSION

The endoscopic sinus surgery is one of the extensively utilized procedures because it is fast, tolerable and minimally invasive technique. The bleeding is a major concern in endoscopic sinus surgical treatment and challenge for anesthesiologists and surgeons as well. Epinephrine is commonly utilized drug for hemostasis in endoscopic sinus surgery and its combination with local anesthetic agent (2%

Lidocaine) is used to boost the hemostasis, decrease the surgical blood loss, better visualization of surgical landmarks by decreasing mucosal blood flow and relieve the pain as well. Along with benefits, it can also have possible adverse effects namely tachycardia, arrhythmias, hypertension and hypotension.

Therefore current study was carried out at ENT Department, Teaching Hospital Dera Ghazi Khan to assess the hemostatic and hemodynamic effects of two different doses of epinephrine (1:100,000 or 1:200,000) during endoscopic sinus surgery. The mean age in Group-A was 39.73+10.736 years while in Group-B was 39.35+11.421 years. The findings of our study are almost comparable with a study undertaken by Moshaver and coworkers who reported that mean patient age in Group-A (1:100,000) was 39.1+11.1 years while in Group-B (1:200,000) was 41.1+12.3 years. However, in a study by Al-Shehri, mean patient age in Group-A (1:100,000) was 38.0 years and in Group-B (1:200,000) was 37.0 years.[16] It is believed that male patients are affected more by sinonasal polyposis than females. A study by Steven and colleagues and Al-Shehri (53.3% in Group-A and 56.7% in Group-B) reported that males were most affected than females.[16,17] The findings of our study also confirmed that majority of the cases in both groups (60.4% in Group-A and 64.6% in Group-B) were males. However, Moshaver and coworkers in their study reported that 50.0% patients in Group-A and 49.0% patients in Group-B were males.[18]

During study blood loss was assessed among patients of both groups who experienced endoscopic sinus surgery and found significant difference between the blood loss of both groups. The patients in Group-B had less blood loss (mean 176.90+5.846 ml) than patients in Group-A (mean blood loss 202.58+12.218 ml) which shows the efficacy of epinephrine dose 1:200,000. However in a recent study by Kermani and associates reported that Group-A patients had less blood loss than Group-B patients. The mean blood loss in Group-A was 83.16+10.01 ml while in Group-B was 108.07+11.68 ml.[19] Another study performed by Günel and collaborators also reported that Group-A patients had less blood than Group-B patients. But in this study dose of epinephrine in Group-B was 1:10,000.[20]

It was found during study that all patients in both groups had normal mean heart rate (<100 bpm) at 0, 1, 2, 3, 4 and 5 minutes but mean heart rate was found better among patients who were given epinephrine dose 1:200,000 (Group-B). The findings of our study are comparable with a study conducted by Al-Shehri and Moshaver and coworkers who also confirmed that mean heart rate was better among patients who were given epinephrine dose 1:200,000.[16,18] Another study by Geelani and teammates asserted that in Group-I (8-10ml of epinephrine 1:200,000 with lignocaine) all patients had normal mean heart rate and in Group-II (8-10ml of epinephrine 1:200,000 with normal saline) all patients had normal mean heart rate except one patient at 5 minutes (108.2+3.38). The results of this study confirmed that patients in Group-I had better mean heart rate than Group-II.[21]

When the mean systolic blood pressure (SBP) was compared in both groups, it was found that all patients in Group-B had normal mean SBP (<120 mmHg) at 0, 1, 2, 3, 4 and 5 minutes but patients in Group-A also had mean normal SBP except at 1 minute (122.58+5.111 mmHg) and at 2 minutes (128.67+4.329 mmHg). Overall better mean SBP was observed among patients of Group-B. In studies by Al-Shehri and Moshaver and coworkers showed comparable results and confirmed that all patients in Group-B had normal mean SBP from 0-5minutes but patients in Group-A had mean normal SBP except at 1 min (127+25 mmHg), 2 min (128+26 mmHg), 3 min (125+25 mmHg) and at 1 min (127.5+27.0 mmHg) and 2 min (128.0+28.7 mmHg) respectively. As far as diastolic blood pressure(DBP) is concerned, study highlighted that all patients in both groups had normal mean DBP (<80 mmHg) at 0-5 minute, however, mean heart rate was found better among patients who were given epinephrine dose 1:200,000. The results of our study are comparable with a study performed by Al-Shehri and Moshaver and coworkers who also reported the similar results at 0-5 minutes

and better mean DBP in group-B.[16,18]

During study quality of surgical field was also compared in both groups and found that Group-B patients had better quality of surgical field than Group-A patients. In Group-B patients mean surgical field grade was 2.19+0.734 while in Group-A was 2.40+0.818. A study done by Moshaver and coworkers also reported that patients in Group-B had better quality of surgical field than patients in Group-A. The results of another study performed by Geelani and teammates also indicated that patients in Group-II (8-10ml of epinephrine 1:200,000 with normal saline) had better quality of surgical field than patients in Group-I (8-10ml of epinephrine 1:200,000 with lignocaine)[18,21]

CONCLUSION

Endoscopic sinus surgery is most frequently utilized surgical treatment for chronic sinusitis. Lidocaine hydrochloride 2% with epinephrine dose of 1:200,000 is more effective during endoscopic sinus surgery than epinephrine dose of 1:100,000 with Lidocaine hydrochloride 2%.

Further studies are required to be carried out on vast level to evaluate the hemostatic and hemodynamic effects of two different doses of epinephrine.

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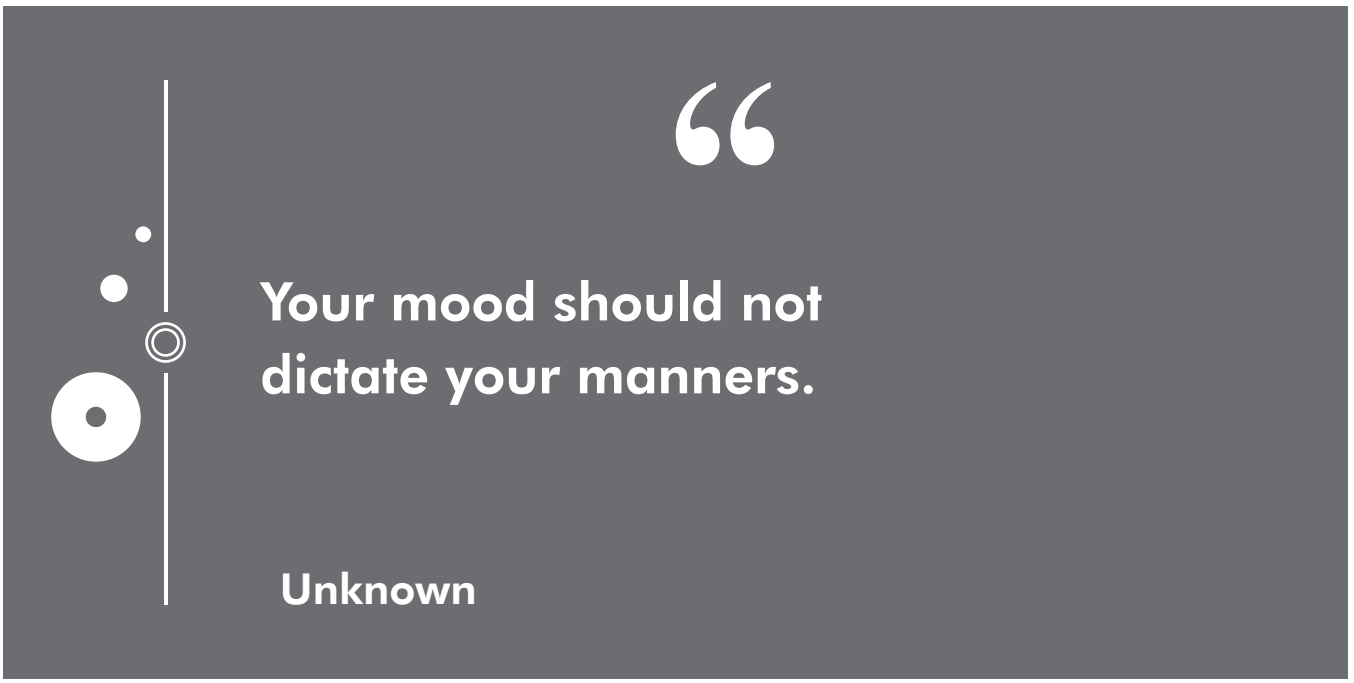

AUTHORSHIP AND CONTRIBUTION DECLARATION

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1	Abdul Malik Mujahid	Con-contributor, conceptualization and design of research work, final approval.	
2	M. Wahid Saleem	Principal contributor, Data collection Statistical analysis, Interpretation of data.	
3	Shahid Ali	Writing of manuscript, Drafting, Literature search.	
4	M. Umair Wahab	Results analysis, Literature search, data collection, Final reviews.	
5	Abdul Shakoor	Statistical analysis, Revision of manuscript, Interpretation of data.	
6	Asma Binte Saad	Review of results and Literature search.	