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Original Research

# Comparison of the Early Results of Supra-Annular and Intra-Annular Aortic Valve Replacement in Isolated Aortic Valve Replacement

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## Abstract

**Objectives:** This study aims to compare the early results of patients who underwent isolated aortic valve replacement (AVR) with supra-annular and intra-annular AVR.

**Methods:** Between 2013 and 2019, 113 patients (77 males; mean age 57.8±16.36 years) who underwent isolated AVR were evaluated. The patients were divided into two groups those who underwent supra-annular (n=59) and intra-annular (n=54) AVR. The most commonly used valves in surgeries St Jude Medical Masters (St. Jude Medical, Minneapolis, MN, USA), (n=35, 30.9%), Sorin Mitroflow (Sorin Group Inc., Mitroflow Division, Canada), (n=32, 28.3%, and Carbomedics Top Hat (Sulzer, Carbomedics, Austin, TX), (n=31, 27.4%).

**Results:** The cross-clamp (XCL) and cardiopulmonary bypass (CPB) times of the patients who underwent supra-annular AVR were found to be significantly higher than the patients who underwent intra-annular AVR. However, there was no significant difference between the two groups in terms of postoperative adverse events. There was no significant difference between the two groups in the postoperative first-week transthoracic echocardiographic (TTE) findings.

**Conclusion:** When comparing supra-annular and intra-annular valve positioning results in patients undergoing isolated AVR, no significant difference was found between the groups in terms of postoperative complications, gradient differences in postoperative TTE, and ejection fractions. Supra-annular valve positioning should be considered, especially in patients with small annulus, in the presence of suitable anatomical features. However, this issue needs to be investigated in future prospective studies with more patients.

**Keywords:** Annular, aortic valve surgery, effective orifice area, heart valve prostheses, patient-prosthesis mismatch

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Surgical aortic valve replacement (AVR) is the gold standard for the treatment of aortic stenosis and regurgitation.[1,2] In AVR, the location where the valve is placed is as important as the features of the prosthetic valve. The implanted valve orifice area is important in the regression of left ventricular (LV) hypertrophy. The smaller effective orifice area (EOA) resulting from small prosthesis implantation may be associated with higher patient-prosthesis mismatch (PPM) and less regression of LV hypertrophy.[3] Instead of intra-annular valve implantation in patients with small an-

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nulus, supra-annular valve implantation can be performed in patients with appropriate anatomical features.

There are a limited number of studies comparing supra-annular prosthetic valves with intra-annular prosthetic valves. In the study by Chambers et al.,[4] the intra-annular MCRI On-X valve (Medical Carbon Research Institute, LLC, Austin, Tex) was hemodynamically superior to the supra-annular CarboMedics Top Hat valve. In the study by Kim et al.,[5] the choice of supra-annular St Jude Medical Regent over intra-annular St Jude Medical Masters resulted in superior transvalvular hemodynamics and LV mass regression in patients undergoing AVR. Guenzinger et al.[6] compared the Medtronic Advantage Supra valve with the St Jude Medical Regent mechanical valve and showed that there were no significant differences in mean pressure gradient, stroke volume, and EOA between the two types of valves.

In the literature, there are similar and different results in the studies conducted in terms of comparing the supra-annular and intra-annular valves concerning each other. Therefore, we designed this study. This study aims to compare the early results of patients who underwent isolated AVR with supra-annular and intra-annular AVR.

## Methods

### Study Population

This study was designed as a retrospective observational single-center study involving a total of 113 patients. Patients over the age of 18 who underwent isolated AVR at the cardiovascular surgery clinic of Kartal Kosuyolu High Specialization Training and Research Hospital between March 2013 and June 2019 were evaluated. Patients with a history of cardiac surgery, undergoing aortic root enlargement procedure, ejection fraction (EF) less than 30%, undergoing emergency surgery, and patients who underwent extracorporeal membrane oxygenation (ECMO) in the preoperative period were excluded from the study. The patients were divided into two groups those who underwent supra-annular (n=59) and intra-annular (n=54) AVR. The most commonly used valves in surgeries were St Jude Medical Masters (St. Jude Medical, Minneapolis, MN, USA), (n=35, 30.9%), Sorin Mitroflow (Sorin Group Inc., Mitroflow Division, Canada), (n=32, 28.3%, and Carbomedics Top Hat (Sulzer, Carbomedics, Austin, TX), (n=31, 27.4%). Surgical indications for AVR were determined according to current clinical guidelines and the operation was planned and discussed by the heart team, but the final decision is left to the discretion of the patient and family.[7] The position in which the valve would be implanted was decided as a result of preoperative TTE findings and intraoperative measurements.

### Surgical Procedure

After the median sternotomy procedure, cardiopulmonary bypass was performed with arterial cannulation from the aorta and venous cannulation from the right atrium. After the cross-clamp was placed, a vent cannula was placed in the right superior pulmonary vein. Moderate hypothermia was achieved. Myocardial protection was provided by antegrade isothermic blood cardioplegia rich in potassium and cardioplegia from the coronary ostia at 15-20 minute intervals. After aortotomy, the aortic valve was reached and the valves with stenosis or regurgitation were resected. The number of prosthetic valves to be implanted was determined by the annulus size. It was decided how the valve would be implanted according to the structure of the annulus and the measurements made. Plegitic sutures were passed one by one and placed on the ventricular side in patients in the supra-annular group and on the aortic side in patients in the intra-annular group. The position of the valve and plegite relative to the annulus is shown schematically in Figure 1.

### Data Collection

All patients' basic demographics, medical histories, laboratory parameters, surgical procedure details, transthoracic echocardiographic (TTE) data, and major adverse cardiac and cerebrovascular events (MACCE),[8] made according to standard definitions, were recorded by reviewing the hospital information management system. For adverse events, results in the postoperative 3-month period were included in the study. TTE findings of all patients in the preoperative period and postoperative 1st-month follow-up were recorded. Severe PPM was defined as <0.65 $cm^2/m^2$ indexed effective orifice area (IEOA).

The study was approved by the Ethics Committee Kartal Kosuyolu High Specialization Training and Research Hospital (2020.09.22) and the study was undertaken by the declaration of Helsinki. Artificial intelligence-assisted technologies in the production of submitted work were not used. Written informed consent was obtained from the patients.

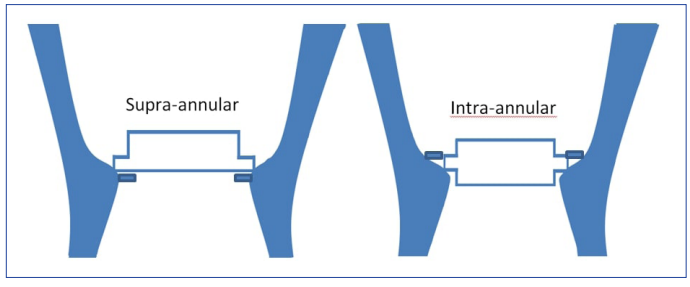


**Figure 1.** The position of the valve and plegite relative to the annulus.

## Statistical Analysis

IBM SPSS Statistics 22 (SPSS Inc., Chicago, Ill, USA) program was used for statistical analysis. The suitability of the parameters to the normal distribution was evaluated by Kolmogorov-Smirnov and Shapiro-Wilks tests. In addition to descriptive statistical methods (minimum, maximum, mean, standard deviation, median frequency), Student's t-test was used for comparisons of normally distributed parameters between two groups, and Mann Whitney U test was used for comparisons of non-normally distributed parameters between two groups. The Chi-Square test, Fisher's Exact Chi-Square test, Fisher Freeman Halton Exact test, and Continuity (Yates) Correction were used to compare qualitative data. Significance was evaluated at the $p<0.05$ level.

## Results

Demographic and preoperative clinical characteristics of the patients are shown in Table 1. The mean age was 57.8±16.36 years and 77 (68.1%) patients were male. There was no significant difference between the two groups in terms of basic demographic characteristics, comorbid conditions, and basic laboratory parameters. No significant difference was found between the two groups in terms of preoperative EF, maximum and mean gradients in the aortic valve, aortic valve areas, and rates of severe aortic stenosis and regurgitation. Aortic stenosis was diagnosed in 83 (73.4%) patients, aortic regurgitation in 30 (26.5%) patients, stenosis and insufficiency in 2 (1.8%) patients, and aortic insufficiency due to infective endocarditis in 1 (0.9%) patient.

The rates of using valve size 19 (10.2%) and 21 (40.7%) were found to be high in patients who underwent supra-annular AVR, and the rates of using valve size 23 (40.7%) and 25 (24.1%) were found to be significantly higher in patients who underwent intra-annular AVR. The distribution chart of valve numbers according to aortic valve replacement is shown in Figure 2.

Intraoperative data of the patients, postoperative adverse events, and TTE findings are shown in Table 2. Of the patients who underwent supra-annular AVR, 42 (71.2%) mechanical valves, 17 (28.8%) bioprosthesis, and intra-

**Table 1.** Demographic and clinical characteristics of the patient and preoperative echocardiographic findings

| | Supra-annular group (n=59) Mean±SD or n (%) | Intra-annular group (n=54) Mean±SD or n (%) | p |
|---|---|---|---|
| Gender male | 40 (67.8) | 37 (68.5) | 1.00[1] |
| Age (years) | 59.44±14.41 | 56±18.23 | 0.27[1] |
| Height (cm) | 167.47±8.42 | 166.39±9.09 | 0.51[1] |
| Weight (kg) | 79.24±12.76 | 75.78±14.39 | 0.17[1] |
| BSA (kg/m$^2$) | 1.91±0.18 | 1.86±0.2 | 0.17[1] |
| BMI (m$^2$) | 28.26±4.19 | 27.39±4.88 | 0.31[1] |
| Hypertension | 30 (50.8) | 23 (42.6) | 0.38[3] |
| Diabetes Mellitus | 17 (28.8) | 14 (25.9) | 0.89[6] |
| COPD | 15 (25.4) | 7 (13.0) | 0.15[6] |
| Cerebrovascular accident | 0 (0) | 1 (1,9) | 0.47[4] |
| Hemodialysis | 2 (3.4) | 0 (0) | 0.49[4] |
| Urea (mg/dL) | 41.36±24.75 | 38.98±13.26 | 0.71[2] |
| Creatinine (mg/dL) | 1.09±1.47 | 0.83±0.21 | 0.67[2] |
| Hemoglobin /g(dl) | 13.11±1.70 | 12.88±1.83 | 0.50[1] |
| Platelet (10$^9$/L) | 236.86±81.56 | 220.54±64.68 | 0.24[1] |
| Normal sinus rhythm | 57 (96.6) | 52 (96.3) | 1.00[4] |
| Atrial fibrillation | 2 (3.4) | 2 (3.7) | 1.00[4] |
| Ejection fraction (%) | 59.44±9.24 | 58.93±9.51 | 0.35[2] |
| Max gradient (mmHg) | 82.76±20.21 | 79.2±23.98 | 0.46[1] |
| Mean gradient (mmHg) | 51.62±14.02 | 47.68±14.54 | 0.21[1] |
| Aortic valve area (cm$^2$) | 0.84±0.21 | 0.82±0,17 | 0.62[1] |
| Severe aortic stenosis | 49 (83.1) | 34 (62.9) | 0.23[5] |
| Severe aortic regurgitation | 11 (18.6) | 19 (35.2) | 0.69[5] |

BSA: body surface area BMI: body mass index, COPD: chronic obstructive pulmonary disease; [1]It was done by Student's T-test. [2]It was done by the Mann-Whitney U test. [3]It was done by the Chi-Square test. [4]It was done by Fisher's Exact test. [5]It was done by Fisher Freeman Halton Exact Test. [6]It was done by Continuity (Yates) Correction.

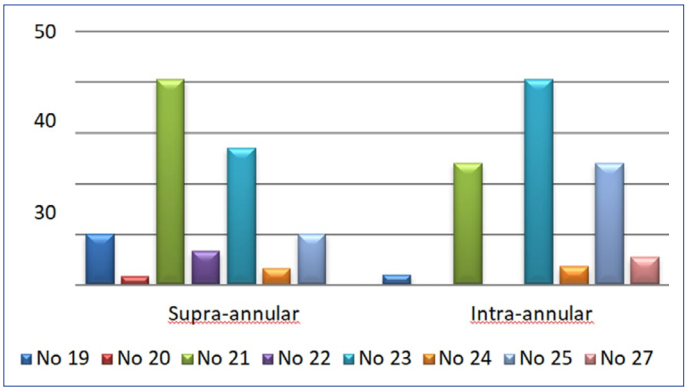


**Figure 2.** Distribution chart of valve numbers according to aortic valve replacement.

annular AVR patients 35 (64.8%) mechanical valves, 19 (35.2%) bioprosthesis valve was applied and there was no significant difference between them (p=0.60, p=0.60, respectively). The mean cross-clamp (XCL) and cardiopulmonary bypass (CPB) times of the supra-annular group (74.44±15.71 min and 106.98±22.06 min) were found to be significantly higher than the intra-annular group (48.31±13.21-76.63±23.41) (p<0.001, p<0.001, respectively). The mean amount of drainage in the first 24 hours of the patients who underwent supra-annular AVR was 613.56±443.62 ml, and there was no difference between the intra-annular group by 505.56±369.3ml (p=0.10). However, the total drainage amount of the supra-annular group (856.78±564.73 ml) was significantly higher than the intra-annular group (695.37±608.84 ml) (p=0.03). The extubation times of the supra-annular group (9.86±3.76 hours) were significantly longer than the intra-annular group (9.3±8.56 hours) (p=0.02). However, there was no statistical difference between the two groups in terms of discharge time (10.51±8.97 days-9.35±9.52 days, p=0.26) No statistical dif-

**Table 2.** Intraoperative data, postoperative complications, and echocardiographic findings

| | Supra-annular Group (n=59) Mean±SD or n (%) | Intra-annular group (n=54) Mean±SD or n (%) | p |
|---|---|---|---|
| Mechanical valve | 42 (71.2) | 35 (64.8) | 0.60[6] |
| Bioprosthetic valve | 17 (28.8) | 19 (35.2) | 0.60[6] |
| XCL time (min) | 74.44±15.71 | 48.31±13.21 | <0.001[1]* |
| CPB time (min) | 106.98±22.06 | 76.63±23.41 | <0.001[1]* |
| Drainage in the first 24 hours (ml) | 613.56±443.62 | 505.56±369.3 | 0.10[2] |
| Total drainage (ml) | 856.78±564.73 | 695.37±608.84 | 0.02[2]* |
| Extubation time (hours) | 9.86±3.76 | 9.3±8.56 | 0.02[2]* |
| Discharge time (days) | 10.51±8.97 | 9.35±9.52 | 0.26[2] |
| Normal sinus rhythm | 54 (91.5) | 50 (92.6) | 0.92[5] |
| Atrial fibrillation | 0 (0) | 1 (1.9) | 0.47[3] |
| Atrioventricular block | 1 (1.7) | 0 (0) | 1.00[3] |
| Temporary pacemaker | 4 (6.8) | 3 (5.6) | 1.00[3] |
| Permanent pacemaker | 3 (5.1) | 0 (0) | 0.24[3] |
| Atrial fibrillation on follow-up | 11 (18.6) | 5 (9.3) | 0.24[6] |
| Revision due to bleeding | 3 (5.1) | 1 (1.9) | 0.62[4] |
| Inotrope need | 8 (13.6) | 15 (27.8) | 0.10[6] |
| IABP | 0 (0) | 3 (5.6) | 0.10[4] |
| Hemodialysis | 3 (5.1) | 1 (1.9) | 0.62[4] |
| Cardiac tamponade | 3 (5.1) | 0 (0) | 0.24[4] |
| Cerebrovascular accident | 0 (0) | 1 (1.9) | 0.47[4] |
| Early mortality | 1 (1.7) | 0 (0) | 1.00[4] |
| Ejection fraction (%) | 58.02±9.36 | 58.42±8.99 | 0.97[2] |
| Max gradient (mmHg) | 29.91±11.06 | 28.19±14.14 | 0.47[1] |
| Mean gradient (mmHg) | 16.36±7.02 | 15.10±8.36 | 0.39[1] |
| Mild paravalvular leak | 6 (10.2) | 4 (7.4) | 0.74[4] |
| Severe paravalvular leak | 2 (3.4) | 1 (1.9) | 0.62[4] |
| Central aortic insufficiency | 5 (8.5) | 1 (1.9) | 0.20[4] |

XCL: cross-clamp, CPB: cardiopulmonary bypass, IABP: intra-aortic balloon pump; [1]It was done by Student's T-test. [2]It was done by the Mann-Whitney U test. [3]It was done by the Chi-Square test. [4]It was done by Fisher's Exact test. [5]It was done by Fisher Freeman Halton Exact Test. [6]It was done by Continuity (Yates) Correction.

ference was found when the two groups were compared in terms of postoperative adverse events (atrial fibrillation, need for pacemaker, need for inotropes, revision due to bleeding, need for intra-aortic balloon pump, hemodialysis, tamponade, cerebrovascular accident, early mortality).

There was no significant difference between the two groups in the postoperative first-month TTE findings in terms of ejection fraction (%58.02±9.36 - %58.42±8.99), maximum gradient (29.91±11.06 mmHg - 28.19±14.14 mmHg) and mean gradient (16.36±7.02 mmHg - 15.10±8.36 mmHg) in the aortic valve (p=0.97, p=0.47, p=0.39, respectively). No statistical difference was found between the two groups in terms of postoperative mild paravalvular leak (6(10.2%) - 4(7.4%)), severe paravalvular leak (2(3.4%) - 1(1.9%)), and central aortic regurgitation 5(8.5%) - 1(1.9%) rates (p=0.74, p=0.62, p=0.20, respectively).

## Discussion

Surgical AVR has been used successfully for many years in aortic valve diseases. Aortic valve disease is often associated with a smaller than normal size aortic annulus. This may result in enlarging the annulus or having to place a smaller prosthesis during aortic valve surgery. Enlarging the annulus may increase postoperative complications. Placement of small prostheses may result in higher residual pressure gradients, and incomplete LV hypertrophy regression, and is also associated with higher PPM as the suture ring reduces the space available for blood flow.[9] Because of this problem, the valve can be implanted supra-annularly instead of intra-annularly in patients with suitable anatomical features. In this way, the orifice of the valve could theoretically be the same size as the patient's tissue annulus without protruding into the prosthetic valve outflow area. With the implantation of supra-annular prosthetic valves, studies have shown good short-term hemodynamic outcomes after AVR.[10,11] The hemodynamic properties of supra-annular prosthetic valves and intra-annular prosthetic valves have been compared, but there are not enough studies in the literature to provide definitive information on this subject.

We did not find any significant difference in postoperative maximum gradient, mean gradient, and EF between patients who underwent supra-annular AVR and patients who underwent intra-annular AVR. Bottio et al.[12] showed that the intra-supra-annular valve (SJM Regent valve and MCRI On-X valve) was hemodynamically superior to the complete supra-annular valve (Carbomedics Top Hat valve) in terms of transprosthetic mean and peak gradients, and effective orifice area. In the study by Kim et al.,[5] mean pressure gradients in postoperative echocardiographic findings of patients with supra-annular aortic valve implanted were found to be lower than in patients with intra-annular aortic valve implanted. However, these results did not show a significant benefit in long-term survival or prevention of major valve-related adverse events. In the study by Guenzinger et al.,[6] similar to our study, no significant superiority was found for either prosthesis in terms of LV mass regression, IEOA, and mean pressure gradient, and it was concluded that there was no additional benefit of supra-annular valve positioning. In our study, early mortality was observed in 1.7% of patients who underwent supra-annular AVR and 0% of patients who underwent intra-annular AVR, and there was no significant difference between them. Similarly, no significant difference was found in terms of mortality time in both groups in the studies by Guenzinger and Chambers.[4,6]

No significant difference was found between the two groups in terms of postoperative adverse events (atrial fibrillation, pacemaker need, inotrope need, revision due to bleeding, need for intra-aortic balloon pump, hemodialysis, tamponade, cerebrovascular accident, early mortality, paravalvular leak, central aortic insufficiency) in our study. Similarly, in the study by Kim et al.,[5] early death rates and incidence of early major morbidity were similar for both groups. Similarly, in the study by Guenzinger et al.,[6] there was no difference between the two groups in terms of the frequency of clinical events and paravalvular leak.

We found that the XCL and CPB times of patients who underwent supra-annular AVR were significantly higher than those of patients who underwent intra-annular AVR. Possibly related to this, although the amount of drainage in the first 24 hours was similar, the total amount of drainage was higher in the supra-annular group. In addition, the extubation time was found to be longer in the supra-annular group. However, there was no statistical difference between the two groups in terms of postoperative adverse events, and the discharge time of the two groups was similar. Similarly, in the study by Kim et al.,[5] the duration of XCL and CPB was found to be longer in patients who underwent supra-annular AVR, and this was attributed to concomitant procedures. While the rate of severe aortic stenosis was higher in the supra-annular group, the rate of severe aortic regurgitation was higher in the intra-annular group. In our study, the duration of XCL and CPB may be longer due to surgical resection of the stenotic valve and complete cleansing of the annulus. In addition, we think that these periods are longer since supra-annular AVR is usually performed on patients with smaller annulus. However, there was no significant difference between the two groups in terms of postoperative adverse events.

The rates of using valve sizes 23 and 25 were significantly

higher in patients who underwent intra-annular AVR. Since the supra-annular valve is frequently preferred in patients with advanced aortic stenosis, valve numbers remained lower than in patients who underwent intra-annular AVR, which this is more frequently preferred in the background of insufficiency.

An important issue to consider during the operation is the distance between the prosthesis profile and the coronary ostia. Especially in cases where there is hypoplasia in the aortic root, supra-annular valves may disrupt the perfusion of the coronary ostia. A case of occlusion of the coronary ostia after AVR in the supra-annular valves has been reported.[13] For this reason, we recommend that supra-annular valves should be avoided, especially in cases where the coronary ostia are located close to the aortic sinus. For this reason, when choosing the valve to be implanted in the patient, it is necessary to examine the anatomical features of the patient in detail.

When we look at the literature, studies show that supra-annular valve implantation is superior to intra-annular implantation, but there are also studies showing that there is no significant difference compared to each other. Therefore, it is still controversial how the valve should be implanted. In our study, however, no significant difference was found between the two groups in postoperative gradient changes, EF, and adverse events. In addition, in many studies, patients who underwent additional surgery in addition to AVR were also included in the study. Patients who underwent additional surgical intervention were excluded from our study, and the relationship between the two groups was tried to be better examined. However, this led to a decrease in the number of our patients. With these results, we can say that we did not find any difference in terms of postoperative adverse events, gradient differences, and EF in patients who underwent supra-annular and intra-annular AVR. For this reason, we think that this problem can be overcome by implanting the valve supra-annularly, in addition to annulus enlargement methods, to implant a valve of appropriate size, especially in patients with a small annulus. Considering that there is no significant difference in the postoperative period, this method may be an additional helpful option for surgeons in difficult operations. However, these findings need to be further investigated in future prospective studies.

## Limitations

One of the most important limitations of our study is its retrospective character and the small number of patients. Although the inclusion of patients with isolated AVR and the removal of concomitant procedures increased the power of the study, we included not only patients with aortic stenosis but also patients with aortic regurgitation due to the small number of patients. The results of the study may have been affected due to the different effects of these pathologies. Due to the retrospective study design, we could not compare these and related parameters between the groups, since we could not reach some TTE findings (IEOA, LV mass, annulus size). In addition, the wide variety of valve brands and the inability to compare mechanical and biological valves separately are important limitations of the study. However, we think that this study will lead to future studies and the issue can be better understood in studies with larger number of patients.

## Conclusion

When the results of supra-annular and intra-annular valve positioning were compared in patients who underwent isolated AVR, we did not find any significant differences between the groups in terms of postoperative complications, gradient differences in postoperative TTE, and ejection fractions. Supra-annular valve positioning should be considered, especially in patients with small annulus, in the presence of suitable anatomical features. However, this issue needs to be investigated in future prospective studies with a higher number of patients.

### Disclosures

**Ethics Committee Approval:** Kartal Kosuyolu High Specialization Training and Research Hospital (2020.09.22).

**Peer-review:** Externally peer-reviewed.

**Conflict of Interest:** None declared.

**Authorship Contributions:** Concept – O.B., T.T.; Design – O.B., T.T.; Supervision – V.B., M.Y.; Materials – T.T., A.Z.; Data collection &/or processing – T.T., A.Z.; Analysis and/or interpretation – O.B., T.T., V.B., M.Y.; Literature search – O.B., T.T.; Writing – O.B., T.T.; Critical review - O.B., T.T., M.Y.

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