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The racial disparity among post transcatheter aortic valve replacement outcomes: A meta-analysis

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ABSTRACT

Background: Racial disparities have been well described in cardiovascular disease. However, the impact of race on the outcomes post - Transcatheter aortic valve replacement (TAVR) remains unknown.
Objective: We aim to evaluate the disparity among the race (black and white) post - TAVR.
Methods: We systematically searched all electronic databases from inception until September 26, 2022. The primary outcome was in-hospital all-cause mortality, and secondary outcomes was myocardial infarction (MI), acute kidney injury (AKI), permanent pacemaker implantation (PPI) or ICD, stroke, vascular complications, and major bleeding.
Results: A total of three studies with 1,02,009 patients were included in the final analysis. The mean age of patients with white and black patients was 82.65 and 80.45 years, respectively. The likelihood of in-hospital all-cause mortality (OR, 1.01(95 %CI: 0.86–1.19), P = 0.93), stroke (OR, 0.83(95 %CI:0.61–1.13), P = 0.23, I2 = 46.57 %], major bleeding [OR, 1.05(95 %CI:0.92–1.20), P = 0.46), and vascular complications [OR, 0.92(95 % CI:0.81–1.06), P = 0.26), was comparable between white and black patients. However, patients with white race have lower odds of MI (OR, 0.65(95 %CI:0.50–0.84), P < 0.001), and AKI (OR, 0.84(95 %CI:0.74–0.95), P = 0.01) and higher odds of PPI or ICD (OR, 1.16(95 %CI: 1.06–1.27), P < 0.001, I2 = 0 %) compared with black race patients.
Conclusion: Our findings suggest disparity post - TAVR outcomes existed, and black patients are at higher risk of MI and AKI than white patients.
Key Clinical Message:

- **What is already known on this topic:** Disparity has been witnessed among patients with cardiovascular disease. However, no studies have drawn a significant association among post-TAVR patients' outcomes

Abbreviations: TAVR, Transcatheter aortic valve replacement; AS, Aortic Stenosis; AA, African American; OR, Odds ratio; CI, Confidence interval; ICD, Implantable cardioverter-defibrillator.

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- **What this study adds:** Among patients who underwent TAVR, there is a difference in the adverse outcomes between black and white race patients. White patients have a lower risk of post-procedure MI and AKI compared with Black patients.
- **How this study might affect research, practice, or policy:** These disparities need to be addressed, and proper guidelines need to be made along with engaging patients with better medical infrastructure and treatment options.

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1. Introduction

Transcatheter aortic valve replacement (TAVR), a minimally invasive procedure, was first conducted on a patient with severe aortic stenosis (AS) in 2002, and later in 2011, it was approved for high-risk severe AS patients by the Food and Drug Administration (FDA) [1,2]. After several trials, the FDA recently approved this procedure for low-risk AS patients [3]. AS is one of the most common valvular diseases, with a 2–7 % prevalence in the elderly patient population (>65 years) [4,5]. TAVR is the recommended procedure for AS, but it is not risk-free and many complications have been outlined in the literature related to this procedure [6]. The major complications reported are bleeding, stroke, acute kidney injury, atrioventricular block and paravalvular leakage [7].

Racial disparities not only have a strong correlation with cardiovascular disease but also impact both treatment and outcomes [8,9]. Previous studies have found that African Americans (AAs) have poorer long-term outcomes if they have non-ischemic heart failure than non-African Americans (non-AAs), and because aortic stenosis (AS) is a common etiology for non-ischemic heart failure [10], the current outcomes of AS among AAs are especially relevant [11]. Racial disparity in the utilization of TAVRs, especially in AAs, has been attributed to several factors, including low insurance rates, lack of physician trust, poor socioeconomic status, and a low rate of referral for specialized procedures [12]. The significantly lower risk of developing severe AS among AAs compared to non-AAs was another reason for racial disparities [12].

Major pivotal trials, such as the PARTNER and CoreValve trials, which established TAVR as an alternative to surgical aortic valve replacement for AS, have reported a very low participation rate among AAs in the United States (US) [13,14]. This low rate of AAs participation in clinical trials is in concordance with prior reports that aim to compare TAVR outcomes between AAs and non-AAs [11,15,16]. As a result, data on racial disparities in TAVR outcomes is extremely limited and has been understudied by larger studies [11]. Here, we took the opportunity to conduct a *meta*-analysis to investigate the impact of racial disparity on different outcomes such as in-hospital all-cause mortality, myocardial infarction, acute kidney injury, permanent pacemaker implantation, stroke, vascular complications, and significant bleeding.

2. Methods

This study was carried out in compliance with the Preferred Reporting Items for Systematic Review and meta-analysis 2020 (PRISMA) guidelines and performed according to established methods [17,18]. A pre-specified study protocol has been registered on PROSPERO (CRD42022363138).

2.1. Study outcomes

The primary outcomes of interest were in-hospital all-cause mortality. The secondary outcomes included stroke, myocardial infarction, permanent pacemaker implantation or implantable cardioverter-defibrillator, acute kidney injury, major bleeding, and vascular complications.

2.2. Search strategy and study selection

We conducted a systematic search in PubMed, Embase, Scopus, and Cochrane Central for articles from their inception until July 20, 2022, using the following keywords and MeSH Terms: (((((((Aortic Stenosis [MeSH Terms]) AND (TAVR[Other Term])) OR (transcatheter aortic valve replacement[Other Term])) AND (racial disparity[Other Term])) OR (Hispanic [Other Term])) OR (African American[Other Term])) OR (disparity[Other Term])) AND (myocardial infarction[MeSH Terms])) OR (Stroke[Other Term]).

Eligible articles were assessed for methodological quality. Two authors (V.J. and A. I) reviewed the abstract and title of the articles for eligibility. The senior author (A.J.) resolved any inclusion-related discrepancy. Studies that were included had all the following parameters: i) patients with diagnosed aortic stenosis and underwent TAVR, ii) studies with patients > 18 years, iii) two-arm studies comparing the black and white patients' outcomes among post-TAVR patients, iv) studies reporting at least one of the desired outcomes and v) prospective, retrospective, or randomized controlled trials were sought to be eligible. We excluded literature or systematic reviews, letters, studies with a single arm, animal studies, and studies with patients < 18 years of age.

2.3. Data extraction and statistical analysis

Data from the eligible studies such as demographic, study design, comorbidity, follow-up, and short-term outcomes between white and black patients were extracted to a spreadsheet by two authors (V.J and A.I).

Baseline continuous variables were summarized in mean (standard deviation), whereas dichotomous variables were described in frequency or percentage. We performed a conventional *meta*-analysis for primary and secondary outcomes and adopted the DerSimonian and Laird random-effect model for the study variations [19]. Outcomes were reported as pooled odds ratio (OR), standard mean difference (SMD) and their corresponding 95 % confidence interval (95 % CI). Statistical significance was met if the 95 % CI did not cross the numeric "1″ and the two-tailed p-value was<0.05. We considered a two-tailed p-value of<0.05 to be statistically significant. In addition, we assessed the between-study heterogeneity using the Higgins I-square (I2) test, with I2 values < 75 % considered mild-moderate and > 75 % considered high [20]. All statistical work, inclusive analysis and graphical illustrations were conducted using STATA (version 17.0, StataCorp).

2.4. Quality assessment

V.J. and A.I independently assessed the quality of the included studies using the Newcastle-Ottawa Scale for cohort studies [21]. The details of the quality assessment are presented in Supplementary Table 1.

3. Results

3.1. Study selection

The preliminary database search using the pre-specified keywords

yielded 394 articles, of which 189 duplicate studies were excluded. One-hundred seventy-five studies were further excluded from the initial post-title and abstract screening based on the inclusion and exclusion criteria and comparison arm. The full-text review was conducted for the remaining thirty studies identified during the search period in which two articles were not retrieved. Twenty-seven studies were excluded as they either had unmatching target populations, were not primary research articles or case reports, or lacked a comparison arm. Hence, three studies that met the eligibility criteria were included in our study (Table 1). The Preferred Reporting Items for Systematic Reviews and meta-Analyses (PRISMA) flow diagram is depicted in Supplementary Fig. 1.

Three studies were included in the final review and analysis [11,15,22]. There were 102,009 patients: 97,831 patients in the white race group and 4178 in the black race group. The mean age of patients with white and black patients was 82.57 and 80.45 years. 47 % of patients in the white group were female, while 61 % were in the black group of patients. Past medical history among patients with white and black race was myocardial infarction (21 % vs 17.6 %), previous stroke (16.7 % vs 18.4 %), while the most common comorbidities were hypertension (86 % vs 90.3 %), and diabetes mellitus (35.3 % vs 48 %). The study characteristics, patients' demographics and comorbidities are presented in Table 1.

3.2. meta-analysis of primary and secondary endpoints

The odds of in-hospital all-cause mortality (OR, 1.01(95 %CI: 0.86–1.19), P = 0.93) were comparable between the white and black race of patients with no heterogeneity between studies (I2 = 0 %) (Fig. 1).

In terms of secondary outcomes, patients with white race have lower odds of MI (OR, 0.65(95 %CI:0.50–0.84), P < 0.001, I2 = 0 %], and AKI [OR, 0.84(95 %CI:0.74–0.95), P = 0.01, I2 = 0 %] compared with black race patients. However, white race patients had significantly higher odds of PPI (OR, 1.16(95 %CI: 1.06–1.27), P < 0.001, I2 = 0 %) compared with black race patients (Fig. 2A-C). Incidence of stroke (OR, 0.83(95 %CI:0.61–1.13), P = 0.23, I2 = 46.57 %], major bleeding [OR, 1.05(95 %CI:0.92–1.20), P = 0.46, I2 = 0 %), and vascular complications [OR, 0.92(95 %CI:0.81–1.06), P = 0.26, I2 = 0 %] was comparable between white and black race patients (Fig. 3A-C).

3.3. Publication bias and risk of bias assessment

Assessment for publication bias using funnel plot did not reveal potential publication bias for all the above outcomes. Results of publication bias are detailed in Supplementary Figs. 2-6. Overall, the included studies were of good quality with a score of 7/9. The details of the quality assessment are presented in Supplementary Table 1.

Table 1
Baseline characteristic of included studies arranged in form of (White/Black race patients).

Variables	Hernadez-Suarez et al., 2019 [15]	Alkhouli et al., 2019 [22]	Minha et al., 2015 [11]
Total Patient, n	33355/1480	64131/2647	345/51
Study Design	Observational	Observational	Observational
Age, years (mean)	81.3/77.7	83/80	83.42/83.65
Female, n	15810/900	30150/1605	172/34
Previous MI, n	4403/155	16091/574	67/8
Previous Stroke, n	4236/206	12025/553	69/8
DM, n	11141/650	23286/1334	109/20
HTN, n	26484/1220	57382/2507	314/47

4. Discussion

To the best of our knowledge, this is the first *meta*-analysis conducted to determine the post-TAVR outcome among different races. The primary outcome of in-hospital all-cause mortality was comparable among people of white and black ethnicity. Secondary outcomes i.e., MI and acute kidney injury, were lower in the white race in comparison to black ethnic patients. However, higher odds of permanent pacemaker implantation were found in white patients in comparison to black patients. The remaining secondary outcomes i.e., incidence of stroke, major bleeding and vascular complications, were comparable among white and black post-TAVR patients.

>400,000 TAVR procedures have been performed over the last decade, and this is all possible because of improvements in technological advancement and operator experience [1]. The number of patients undergoing TAVR has doubled annually over the last several years. However, despite this tremendous increase in TAVR procedure, the percentage of African American patients receiving this procedure is very low compared to Caucasians (3.8 % vs 93 %) [23], which is agreeable with the results of this study. This disparity in implantations of TAVR in African American patients can be due to differences in the incidence of the disease, with black patients having a much lower incidence of aortic stenosis, aortic stenosis-related hospitalization and less severity of disease [16,22,24,25]. It has also been attributed to various factors including poor socioeconomic state, lack of physician trust among minorities and lower likelihood of being referred to specialized procedures [11,22,26,27].

Despite this huge difference in implantations of TAVR, studies conducted by Minha S et al., Hernandez-Suarez D et al., and Alkhouli M et al failed to find any significant difference in post-TAVR outcomes [11,15,22]. While our study found similar results for in-hospital mortality, stroke, major bleeding and vascular complications, the results for MI, acute kidney injury and permanent pacemaker implantation were contradictory to the three studies. This difference could be explained by the larger small size of AA patients this *meta*-analysis was able to analyze.A similar trend of black patients having worse clinical outcomes (higher mortality and 30-day readmission rate) post-Surgical Aortic Valve Replacement (SAVR) was observed among some studies [15,28]. However, the exact reason for these differences remains to be clearly understood. Additionally, the same study which showed that these differences exist following SAVR also revealed that such differences did not exist among patients that were undergoing TAVR [28]. Therefore, it is imperative for controlled and standardized studies to be conducted to analyze whether race is an independent risk factor for complications following TAVR.

TAVR, being the procedure of choice for patients with severe AS and has been approved by the FDA for low-risk aortic stenosis patients as well, has limited data available on its clinical outcome among different races. For the first time in the literature, our study showed significant differences among different races in post-TAVR patients. It is the need of an hour to conduct a large trial to evaluate the difference in clinical outcomes among different races and to find out why there is a huge difference in implantations of TAVR in the African American community compared to Caucasians.

4.1. Limitations

The major limitation of this *meta*-analysis was the inclusion of observational studies which are susceptible to confounding bias and selection bias. Secondly, long-term outcomes for all studies were not available. We were not able to perform subgroup analysis as only three studies were included in the analysis, hence sensitivity analysis and funnel plots have not been conducted. Finally, all studies were conducted in the United States, thus these results are difficult to generalize.

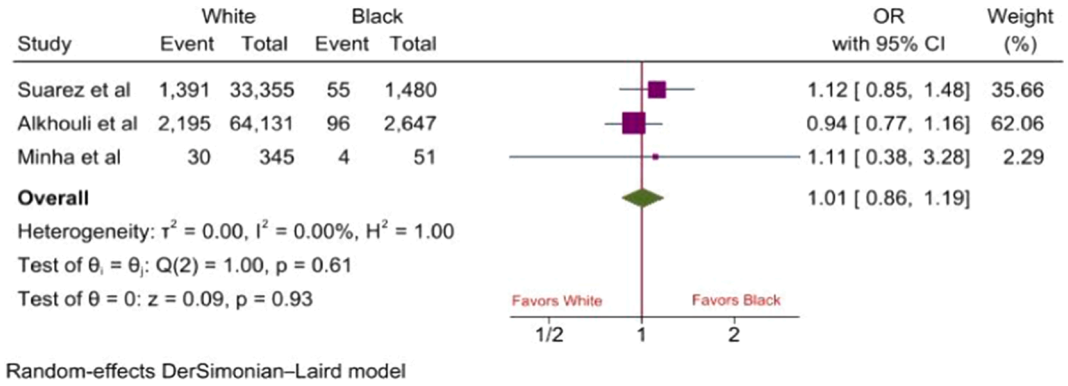
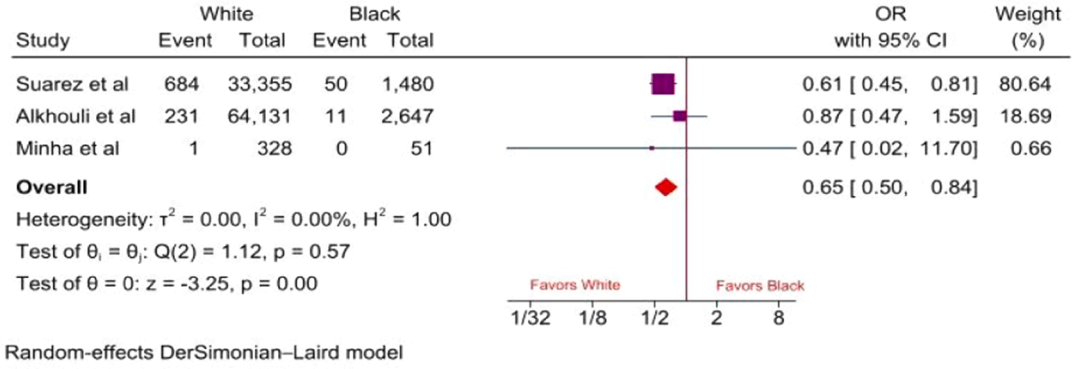
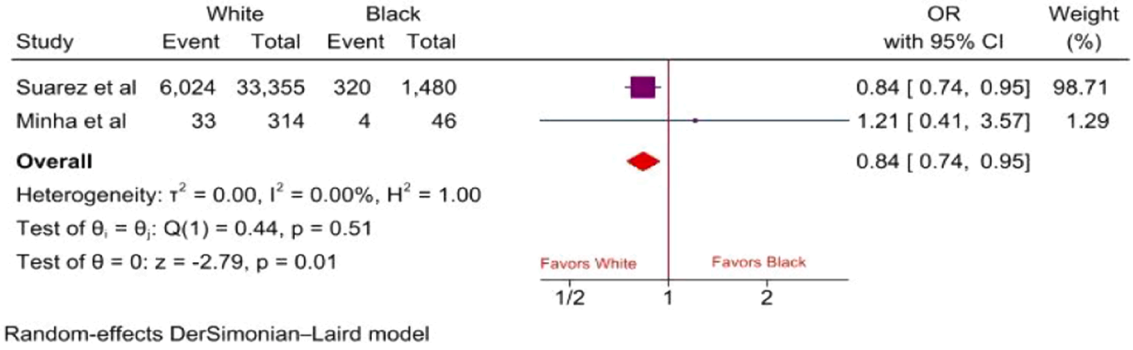


Fig. 1. Forest plot of primary outcomes: In hospital all-cause mortality.

A: MI



B: AKI



C: PPI

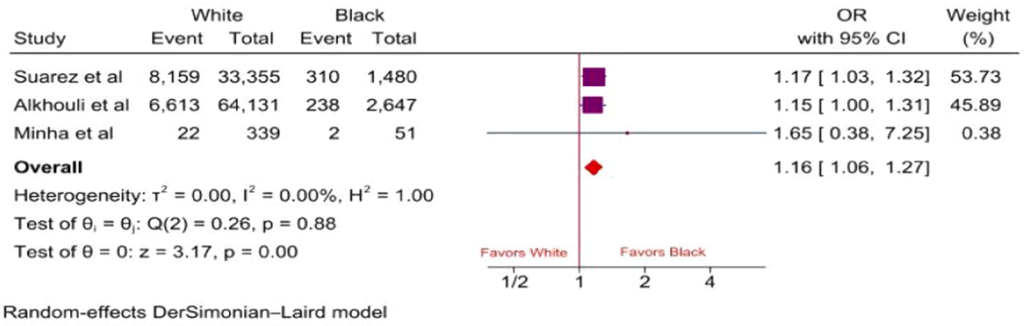


Fig. 2. Forest plot of secondary outcomes: A) MI, B) AKI, C) PPM.

5. Conclusion

TAVR is the mainstream treatment modality for patients with severe AS regardless of their risk profile, however it is still associated with complications. Previous evidence suggests that there was no disparity among patients in the utilization of TAVR based on race. The results of

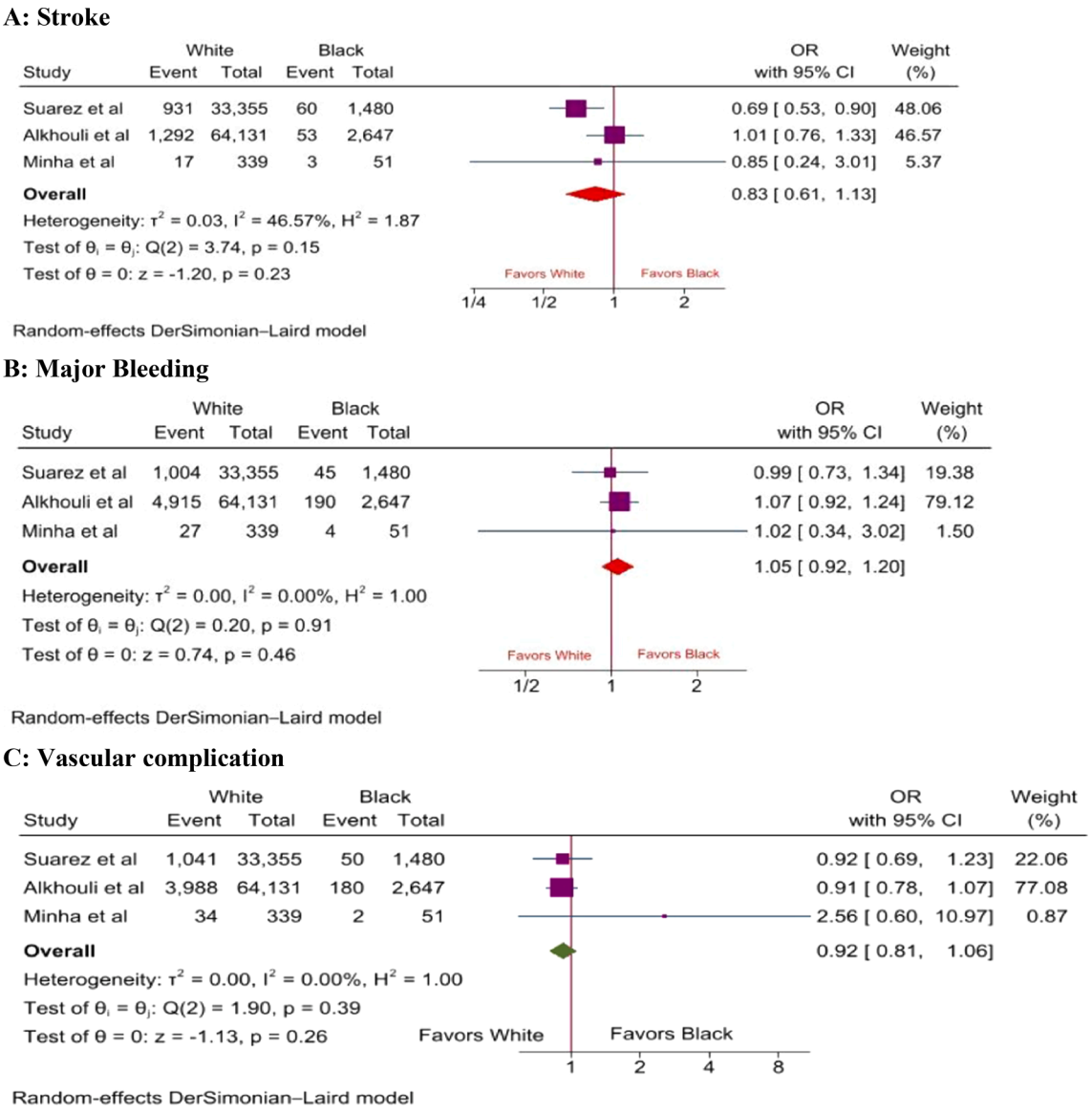


Fig. 3. Forest plot of secondary outcomes A) Stroke, B) Major Bleeding, C) Vascular complication.

this *meta*-analysis suggest that a racial disparity exists in complications associated with TAVR that include occurrence of MI and acute kidney injury which were lower in white patients. Additionally, there were higher rates of permanent pacemaker implantation in white patients post-TAVR. Further studies will be required to further explore racial disparities in receiving TAVR and complications associated with the procedure. Furthermore, newer trials assessing TAVR should include a higher number of non-white patients. Proper policies must be created to engage patients with better medical interventions.

CRediT authorship contribution statement

Vikash Jaiswal: Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Writing – review & editing. **Song Peng Ang:** Formal analysis, Investigation, Writing – review & editing. **Muhammad Hanif:** Writing – original draft. **Mittal Savaliya:** Writing – original draft. **Ananya Vadhera:** Writing – original draft. **Nishchita Raj:** Writing – original draft. **Asmita Gera:** Writing – original draft. **Savvy Aujla:** Writing – original draft. **Farshid Daneshvar:** Writing – original draft. **Angela Ishak:** Writing – review & editing. **Madeeha Subhan Waleed:** . **Victor Hugo Aguilera-Alvarez:** . **Sidra Naz:** . **Maha Hameed:** . **Zarghoona Wajid:** .

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Ethical approval

Since this is a review article, ethical approval was not required.

Source of funding

None.

Ethical approval

As this is a review article, ethical approval was not required. Prospero registration Number: CRD42022363138.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2023.101170.

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