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RESEARCH

Efficacy and safety of sagittal synostosis surgery in older (> 12 months) patients: a systematic review and meta-analysis

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Abstract

Purpose Sagittal synostosis is the most common isolated craniosynostosis. Surgical treatment of this synostosis has been extensively described in the global literature, with promising outcomes when it is performed in the first 12 months of life. However, in some cases, patients older than 12 months arrive at the craniofacial center with this synostosis. A comprehensive study on efficacy and perioperative outcomes has yet to be fully explored in this population. This systematic review and meta-analysis aimed to assess the available evidence of surgical outcomes for the treatment of sagittal synostosis among older patients to analyze the efficacy and safety of synostosis surgery in this unique population.

Methods PubMed, Embase, and Scopus were searched for studies published from inception to March 2024 reporting surgical outcomes of synostosis surgery in older patients (> 12 months) with isolated sagittal synostosis. The main outcome was the reoperation rate, with secondary endpoints including transfusion rates, aesthetic outcomes, and surgical complications.

Results Nine studies were included in the final analysis. The pooled proportion of the reoperation rate was 1%. The rate of excellent aesthetic results was 95%. The need for transfusion associated with the procedures was 86%, and finally, surgical complications attained a pooled ratio of 2%, indicating minimal morbidity associated with the surgical repair.

Conclusion Sagittal synostosis surgery is a safe and effective procedure to perform in older patients; this meta-analysis suggests that open surgery confers a significant rate of excellent aesthetic results with a low reoperation rate and minimal complications associated with the intervention. Future research with direct comparisons among different techniques will validate the findings of this study, which will all contribute to the rigor of synostosis management.

Keywords Craniosynostosis · Isolated sagittal synostosis · Surgery · Outcomes · Older patients

Introduction

Premature fusion of the sagittal suture causes sagittal synostosis, the most common form of craniosynostosis. It accounts for more than half of all single-suture synostosis cases and occurs in approximately 1 in 2000 live births [1, 2]. Sagittal synostosis results in several characteristic phenotypes, depending on the extent and location of the fusion along the sagittal suture. It typically presents as dolichocephaly or scaphocephaly (i.e., "boat-shaped skull"), where the skull's lateral growth is restricted, causing compensatory elongation in the anterior-posterior direction. This results in a long and narrow head shape with a prominent occiput [3]. Apart from the cranial deformity resulting from premature suture closure, impaired brain growth may also occur, potentially leading to intracranial hypertension (ICH) and associated complications [3, 4]. Surgery is offered to patients with sagittal synostosis to correct the skull deformity and prevent ICH [5]. Surgical management aims to restore morphology and permit skull expansion for the developing brain [6, 7].

Two primary surgical techniques are often used to treat sagittal synostosis: (1) endoscopic strip craniectomy, a

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minimally invasive procedure generally preferred for infants under 6 months due to better skull remodeling potential and brain expansion velocity at this age, and (2) open calvarial vault remodeling (CVR), a more invasive technique often chosen for older infants and toddlers due to their thicker cranial bones and reduced skull remodeling capacity [5, 8]. While opinions vary among institutions regarding the optimal timing and technique, the patient's age appears to significantly influence the surgical approach selected for sagittal synostosis. Generally speaking, earlier treatment (< 12 months) is associated with better outcomes and fewer complications [7, 9, 10]. While surgeons aim to correct sagittal synostosis early, some patients present for the first time at older ages (≥ 12 months), when their thicker cranial bones require a more invasive open surgical procedure [11]. Previous reports assessing the efficacy and safety of surgical treatment for sagittal synostosis in older patients have had limited sample sizes, which has led to uncertainty about the clinical outcomes and safety of open surgery in this age group.

Given the possible implications of a thicker and less malleable calvarial bone on surgical success in older patients, it is vital to better understand postoperative outcomes to offer accurate prognoses. Therefore, we evaluated the safety and efficacy of late, open surgery (≥ 12 months) for patients with isolated, non-syndromic sagittal synostosis through a systematic review and single-arm meta-analysis, specifically focusing on the reoperation rate, aesthetic outcomes, surgical complications, and the need for transfusion in this population.

Methods

This systematic review and single-arm meta-analysis followed the methodological guidelines set forth in the Cochrane Handbook for Systematic Reviews of Interventions and adhered to the reporting structure outlined by the Cochrane Collaboration's Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. The review protocol was registered with the International Prospective Register of Systematic Reviews (PROSPERO), under registration number CRD42024538499.

Eligibility criteria

Studies were included if they (1) involved patients diagnosed with isolated sagittal synostosis; (2) had patients with a mean age ≥ 12 months; (3) surgery was focused on sagittal synostosis correction; (4) reported outcomes including reoperation rate, aesthetic outcome, surgical complications, and need for transfusion; and (5) included 5 or more patients. Studies were excluded if (1) no relevant outcomes were reported; (2) the patients described were treated for syndromic or multiple suture craniosynostosis; (3) the patients received treatment at an older age due to a relapse of a previous sagittal synostosis surgery; (4) surgery was done to alleviate other anomalies (i.e., Chiari malformations or hydrocephalus); or (5) they were editorials, reviews, or case reports. The selection process was performed by two independent reviewers and verified for congruence.

Study selection

We systematically searched PubMed, EMBASE, and Scopus from inception to February 2024 with the following search terms: "Sagittal synostosis" OR "Isolated sagittal synostosis" AND "Older patients" OR "Older age" OR "Older" AND "> 12 months" OR "> 1 year" AND "treatment" OR "surgery" AND "reoperation" AND "transfusion" AND "outcomes." The search was limited to studies in the English language. To avoid missing any qualified studies, literature reviews and literature citations were searched.

Data extraction and statistical analysis

Two researchers independently assessed papers for inclusion and extracted data from complete texts and published appendices. Each investigator independently verified the other's data extraction. Consensus or the senior author resolved disagreements. The analysis of the pooled proportion was done with R-version 4.3.3 (R Foundation for Statistical Computing) using the *Meta* and *Metafor* packages. Cochran's Q test and I^2 statistics were used to assess for heterogeneity. Significant heterogeneity was defined as $I^2 > 50\%$.

Endpoints of interest

The primary outcome of interest was the reoperation rate. Reoperation was defined as any surgical procedure done to correct any unsatisfactory aesthetic, relapse, and bone defect or to control ICH after the initial surgery. Reoperation conducted for the removal of palpable wires or hardware, decompression of Chiari malformation, or drainage of hematoma, abscess, or empyema were not included in the primary outcome.

Secondary endpoints included the following: (1) transfusion rates, which were defined as transfusion during the intraoperative or postoperative period; (2) favorable aesthetic outcomes following the procedure, as reported by the parents; and (3) surgical complications, including any adverse event secondary to the surgical approach (e.g., infections, venous air embolisms, hematomas, and CSF leaks).

Results

The initial search found 131 records in the databases searched. After eliminating duplicates, reviewing articles by titles and abstracts, and full-text review, 9 studies were chosen, and 129 patients were analyzed. We performed a single-arm meta-analysis of all the studies included to evaluate the efficacy and benefits of sagittal synostosis surgery in older patients. In Table 1, we detailed each study's characteristics. Figure 1 also describes the study's selection process.

Pooled analysis of all studies

Reoperation was the major outcome of our analysis, with 5studies included and 99 patients analyzed. The pooled proportion of reoperation was 1% (95% CI 0–3%, $p=0.77$; $I^2=0\%$) (Fig. 2). One of the key drawbacks of performing surgery on older patients is the necessity to realize open surgery, which results in wider exposures and a higher risk of bleeding requiring blood transfusion. This secondary outcome of transfusion rates, which included both intraoperative and postoperative blood transfusions, was included in six studies. In this analysis, 86% (95% CI 74–97%, $p=0.03$;, $I^2=59\%$) of the patients needed transfusion after the sagittal synostosis surgery (Fig. 3).

Another outcome of interest was the rate of favorable aesthetic outcomes following the procedure. Four studies were included, providing data on 29 of the 129 patients and a pooled proportion of 95% (95% CI 85–100%, $p=0.42$, $I^2=0\%$) (Fig. 4). Lastly, another key consideration of sagittal synostosis surgery in older patients is the possibility of complications associated with the procedure.

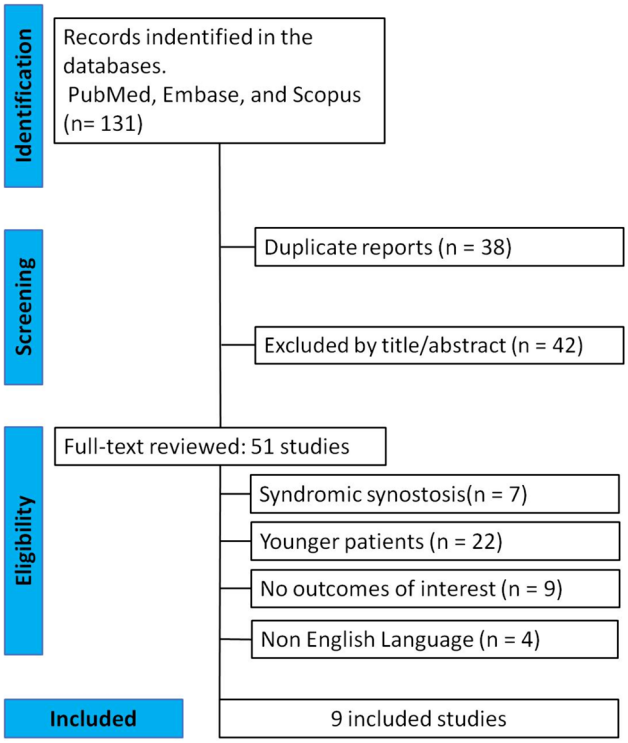

Fig. 1 PRISMA flow diagram of study screening and selection

Table 1 Characteristic of studies included in the meta-analysis

Author	Sample size	Mean age (SD)	Male/female	Mean operative time	Mean blood loss	Mean CI pre-op/post-op	Mean hospital length	Follow-up
Chi et al. [11]	44	29 ± 16 months	35/9	247 ± 65 min	326 ± 190 mL,	67 / 74.2	3.4 ± 0.8 days.	12.2 ± 3 months
Engel et al. [12]	10	15.77 ± 2.73 months	N/A	130 ± 34.64 min	N/A	66.38 /74.38	7.2 ± 1.93 days	62.82 ± 30.12 months
Hudgins et al. [13]	9	37.2 ± 14.4 months	7/2	317.7 ± 42.3 min	483.3 ± 334.5 mL	N/A	5 ± 0.9 days	N/A
Kang et al. [14]	23	83.4 ± 97 months	23/8	172.7 ± 43.2 min	N/A	N/A	6 ± 1 days	22.8 ± 19.2 months
Macmillan et al. [15]	5	50.6 ± 5 months	3/2	411.4 ± 101.6 min	930 ± 460.4mL	N/A	3.2 ± 1.6 days	13.8 ± 6.8 months
Oh et al. [16]	7	20.4 ± 8 months	4/3	201 min	N/A	67.9/73.5	4.6 days	37.1 ± 28.1 months
Rottgers et al. [17]	10	31.2 ± 18 months	9/1	324 min	544 ml	65.3 / 69.2	4.1 days	2.24 years
Smyth et al. [18]	7	4.6 ± 3 years	N/A	312 ± 15.6 min	1519 ± 756 mL	65.6 /71.2	5 ± 0.5 days	12 months
Weinzweig et al. [19]	14	36.5 ± 23 months	13/1	N/A	N/A	N/A	N/A	11.8 ± 1.4 months

SD Standard Deviation, *N/A* Not Available, *min* Minutes, *CI* Cephalic Index

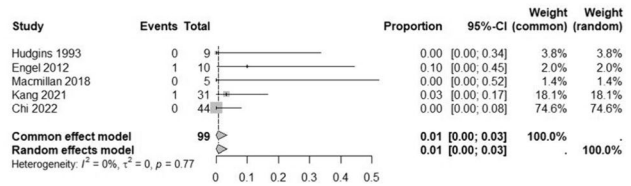

Fig. 2 Results for reoperation rate

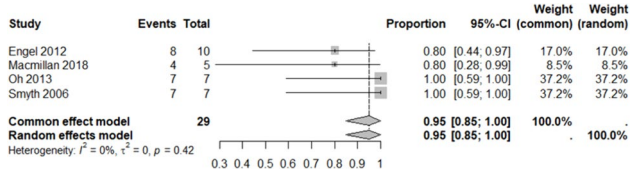

Fig. 4 Results for favorable aesthetic outcomes

Venous air embolism, postoperative infections, CSF leaks, and sagittal sinus injuries were included in eight studies, with the pooled proportion being 2% (95% CI 0–5%, p = 0.05, I^2 = 50%) (Fig. 5).

Quality assessment

Two independent investigators assessed the quality of the included studies using ROBINS-I for non-RCTs and reported their findings in a risk-of-bias table. Any disagreement was resolved by discussion. It resulted in a moderate overall risk-of-bias (Table 2).

Discussion

In this systematic review and single-arm meta-analysis of nine studies with 129 patients, we evaluated the efficacy and safety of performing open surgery on patients aged 12 months or older with isolated sagittal synostosis. Key findings include: (1) a low reoperation rate of 1% across 5 studies involving 99 patients; (2) a significantly elevated transfusion rate of 86%, based on data from 6 studies; (3) a 95% rate of favorable aesthetic outcomes among 29 patients in 4 studies; and (4) minimal postoperative complications such as venous air embolism, infections, CSF leaks, and sagittal sinus injuries, occurring in 2% of cases, as reported in 8 studies.

Reoperation rate and aesthetic outcomes

Satisfactory correction rates in craniosynostosis surgery depend on various factors, with the age at surgery being a major one. Most reports indicate that aesthetic results are generally considered as excellent or good in sagittal synostosis corrections [20, 21]. Nevertheless, a minority of patients may experience unsatisfactory outcomes, necessitating a repeat operation [21–23]. Despite the variety of surgical techniques reported in the literature, the reoperation rate remains very low across them all [24]. The average reoperation rate reported for open procedures is 7.6%, including revisions for aesthetic reasons, relapses, or increased intracranial pressure (ICP) [24, 25]. For patients under 12 months, the primary reason for reoperation is related to the inherent risk of recurrence [26, 27]. In a series of 79 children who underwent early extended strip craniectomies reported by van Veelen et al., 4 patients required reoperation due to elevated ICP. Collmann et al. observed 181 children who had surgery for scaphocephaly, and 11 required a second operation, with raised ICP identified in 6 of them during follow-up [28]. Arts et al. reported an overall revision rate of 4.3% in a retrospective cohort study comparing endoscopic and cranial vault remodeling [29]. Our results revealed a lower reoperation rate compared to previously reported studies, which could be attributed to the shorter follow-up periods reported in studies of older patients with sagittal synostosis and the lower number of patients described in the literature.

From an aesthetic perspective, the results vary significantly depending on the extent of the initial deformity, the patient's age at the time of surgery, and the surgical technique used. Subjective measurements of aesthetic outcomes have traditionally been useful indicators for assessing the effectiveness of surgical correction in synostosis cases [9]. Various techniques have been used to treat the premature fusion of the sagittal suture [30, 31], and most studies comparing aesthetic outcomes among different techniques

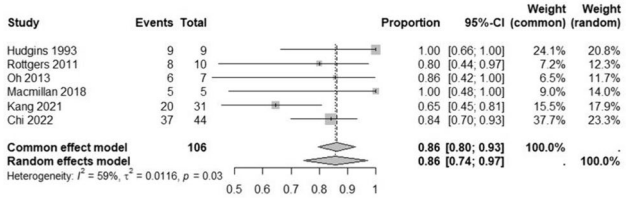

Fig. 3 Results for need of transfusion

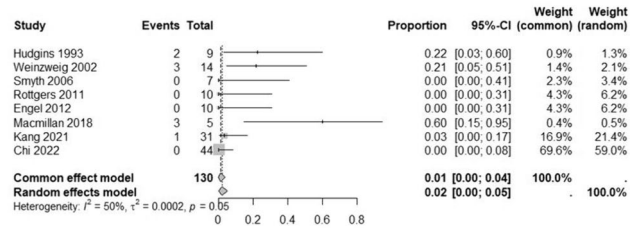

Fig. 5 Results for complications

Table 2 Risk of bias summary for non-randomized studies (ROBINS-I)

Study	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall risk of bias judgement
Chi et al. [11]	Low	Low	Low	Low	Low	Low	Low	Low
Engel et al. [12]	Low	Low	Low	Low	Low	Low	Low	Low
Hudgins et al. [13]	Moderate	Moderate	Low	Low	Moderate	Moderate	Low	Moderate
Kang et al. [14]	Moderate	Low	Moderate	Moderate	Low	Moderate	Low	Moderate
Macmillan et al. [15]	Moderate	Low	Moderate	Moderate	Serious	Low	Low	Serious
Oh et al. [16]	Low	Low	Low	Moderate	Critical	Moderate	Low	Critical
Rottgers et al. [17]	Low	Low	Low	Low	Low	Low	Low	Low
Smyth et al. [18]	Low	Low	Low	Low	Moderate	Low	Low	Moderate
Weinzweig et al. [19]	Low	Low	Low	Low	Critical	Low	Low	Critical

show inconclusive results. Millesi et al. evaluated aesthetic outcomes after surgery in a cohort of patients with non-syndromic sagittal suture synostosis. Depending on their age, patients underwent either an extended midline strip craniectomy (for those < 4 months old) or a modified pi procedure (for those ≥ 4 months old) [32]. In their findings, no differences in aesthetic outcomes were found based on the type of surgical procedure performed at the last follow-up visit. Chowdhury et al. evaluated the aesthetic outcomes of 167 patients with sagittal synostosis who underwent surgery: 83 underwent spring-assisted cranioplasty, 76 underwent CVR, and 5 underwent a "hybrid" procedure combining CVR with springs. While the group that received CVR had better aesthetic outcomes compared to the others, most of these concerns were minor and did not require reoperation [33]. Although aesthetic results are often based on subjective assessments and should be interpreted with caution, most series report excellent or good outcomes. Our meta-analysis showed similarly high rates of excellent aesthetic outcomes in older patients. The included studies employed various correction techniques with comparable aesthetic results, including the modified Pi technique, clamshell craniotomy, modified Melbourne technique, and modified Pi technique with fixed distracters [12, 15, 16, 18].

A helpful measure for assessing a child's head shape is the cephalic index (CI), which has been used to assess surgical outcomes in synostosis surgery [34, 35]. Posnick et al. found that the CI is a useful quantitative method for comparing skull shape in patients before and after sagittal synostosis surgery [36]. In a retrospective analysis by Frostell et al., the mean CI increased from 69 ± 3 to 87 ± 5 in patients with non-syndromic sagittal synostosis who were treated at a mean age of 4.1 ± 3.1 months. Younger patients showed a larger increase in CI compared with older patients [37]. Of the studies analyzed, only 5 provided data on preoperative and postoperative CI for patients treated at older ages, with an average change in CI from 66.4 to 72.5%, which is a smaller change compared to younger patients [11, 12, 15, 17, 18]. Normal values of CI have been reported to range between 74 and 80 in males and 73 and 79 in females [38]. The results of our study show that, despite an increase in CI measurement present in older patients after surgical correction of sagittal synostosis, the final CI is close to a low-normal value, demonstrating that a lower CI change is expected in this population. Despite the high rate of favorable aesthetic outcomes present in our results, we have to be cautious, knowing that CI measurements have been previously reported to have at least 4% variability among evaluators [39], and more importantly, the manner in which aesthetic outcomes are reported in craniosynostosis surgery is still debatable. In this study, we focus on the reports of the parents after the surgical procedure as favorable or not favorable.

Need of transfusion

Our findings also revealed high transfusion rates during the perioperative period among the evaluated patients, consistent with existing literature that highlights the significant blood loss and transfusion requirements associated with

open surgical techniques for synostosis correction. Historically, craniosynostosis surgery has been linked to significant blood loss, with most patients requiring perioperative blood transfusions [39]. Current transfusion rates for sagittal synostosis can be as high as 90%, with higher rates seen with open surgery techniques [40, 41]. To reduce perioperative transfusion rates, various strategies have been employed, including antifibrinolytics, preoperative erythropoietin, cell salvage, standardized perioperative transfusion protocols, and preoperative iron supplementation [42].

Previously, patient age at the time of surgery was thought to be linked with greater blood loss and a higher need for transfusion due to increased cranial thickness [43]. However, a recent retrospective cohort study by Villavisanis et al. found that while parietal bone thickness does increase with age, age itself was not an independent factor contributing to thicker parietal bones [44]. Instead, transfusion rates are more closely related to the surgical technique used to correct sagittal synostosis. A meta-analysis by Goyal et al. showed that endoscopic correction required significantly fewer transfusions compared to open procedures [45].

Complications

Open surgery has been linked with a higher risk of complications due to the wider exposure required, more extensive calvarial bone remodeling associated, and longer hospital stays [46, 47]. A recent survey of craniofacial surgeons found that 93.6% of them used postoperative ICU care for patients after various open scaphocephaly surgery techniques, despite contrasting perioperative risk profiles [47].

Similar to our study, complication rates for sagittal surgery in the current literature range from 0 to 16.5%, with higher rates found in patients with syndromic synostosis [48–50]. Common complications in craniofacial surgeries include CSF leaks, reactions to foreign materials, subgaleal hematomas, major bleeding, infections, and air embolism. Although rare, major complications like sagittal sinus opening, major dural tears, or injuries to the cortex should always be considered [51]. Despite the need for wider exposure to achieve aesthetic results with open techniques, some studies suggest that operating at a younger age could lead to higher complication rates due to these patients' lower tolerance for blood loss, recommending delaying surgery until 6–8 months of age when patients can tolerate more blood loss [52, 53]. In 2014, Doumit et al. presented an internet-based questionnaire to 102 craniofacial surgeons in 14 countries across 4 continents, collecting data on the preferred timing of surgery. For patients with sagittal synostosis younger than 4 months, 76% of respondents recommended surgery, while 24% suggested waiting until 6 months [54]. However, the vast majority agreed that surgery should be performed before 12 months of age to avoid increased bone thickness [55].

Surgical approaches and outcomes correlations

A number of studies have compared the outcomes of different techniques for the management of sagittal synostosis. These studies have already highlighted some of the differences between the existing techniques in younger patients [56, 57]. In our results, we also find different techniques reported in the treatment of sagittal synostosis in older patients; however, in our study, we do not find any correlation between the outcomes and the surgical technique described for the surgical correction. Similar results has been addressed by Galiay et al. in a retrospective multicentre study comparing the morphological outcome of 8 techniques used for the management of sagittal synostosis; in their results, no significant difference in morphological outcomes was observed between the techniques described. However, the majority of techniques showed a tendency for relapse. Further, the more invasive procedures at older ages seem to lead to larger intracranial volume compared to less invasive techniques at younger ages [13]. The utilization of a myriad of techniques in small cohorts of individual cases could change the prognostic value of the expected outcomes; in that order, future comparison studies among different surgical approaches could drive to interesting data in older patients affected with sagittal synostosis.

Limitations

Our study has important limitations. Firstly, none of the included studies were randomized. Secondly, some outcomes demonstrated significant heterogeneity, likely due to differences in the ages at which patients underwent surgery. Additionally, patients who present with sagittal synostosis at older ages are relatively rare in craniofacial centers, and no standardized treatment protocol currently exists. This, along with variations in surgeons or surgical techniques, may account for the high heterogeneity observed.

Conclusion

Surgical correction of sagittal synostosis in older patients ($\geq$ 12 months old) is a safe procedure that can achieve low rates of reoperation and complications with the surgical intervention. Despite the high rates of favorable aesthetic outcomes, cautiousness is warned, recognizing the lower increase in postoperative CI in this population and the debatable ways for aesthetic measurement in craniosynostosis surgery.

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Author contributions All authors contributed to the study conception and design. Conception and design of the research were performed by F.G.P. Acquisition of data was done by F.G.P., B.F., and A.P. Analysis and interpretation of the data were performed by F.G.P., G.G.G., O.M., and H.A.R. The first draft of the manuscript was written by F.G.P. Critical revision of the manuscript for intellectual content was performed by B.F., I.G., and J.F.P., and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Data availability No datasets were generated or analyzed during the current study.

Declarations

Conflict of interest The authors declare no competing interests.

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