Cureus
Part of SPRINGER NATURE

Open Access Original Article

Comparison of Short-Term Postoperative Outcomes Following Open Aortofemoral Bypass With and Without Epidural Analgesia

Review began 10/08/2026
Review ended 10/19/2026
Published 10/27/2026

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DOI: 10.7759/cureus.118679

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Abstract

Background

Open aortofemoral bypass remains an established revascularization procedure for extensive aortoiliac occlusive disease. Although epidural analgesia can improve postoperative pain control after open abdominal aortic surgery, its association with short-term outcomes specifically following aortofemoral bypass for occlusive disease remains insufficiently characterized. We aimed to compare 30-day postoperative composite morbidity and selected recovery outcomes between patients receiving general anesthesia with thoracic epidural analgesia and those receiving general anesthesia with systemic opioid analgesia alone after elective open aortofemoral bypass.

Methods

This retrospective comparative observational study included 120 patients undergoing elective open aortofemoral bypass for aortoiliac occlusive disease at Bangladesh Medical University, Bangladesh, between January 2021 and December 2024. Patients were classified according to the analgesic technique documented in their medical records: epidural analgesia (Group E, n=60) or systemic opioid analgesia (Group G, n=60). The primary outcome was the occurrence of at least one postoperative complication within 30 days. Secondary outcomes included postoperative pain scores, pulmonary complications, mechanical ventilation duration, time to ambulation, time to oral feeding, intensive care unit (ICU) stay, hospital stay, and 30-day mortality.

Results

Baseline demographic and clinical characteristics and intraoperative variables were comparable between the groups. Composite postoperative morbidity was significantly lower in Group E than in Group G (14/60 (23.3%) vs. 30/60 (50.0%); χ^2=9.19, p=0.002). Pulmonary complications were also less frequent in Group E (7/60 (11.7%) vs. 17/60 (28.3%); χ^2=5.21, p=0.023). At 24 hours, the mean visual analog scale pain score was lower in Group E than in Group G (3.2 ± 1.1 vs. 5.9 ± 1.5; p<0.001). Group E also had shorter ICU stays (2.3 ± 0.9 vs. 3.7 ± 1.4 days), hospital stays (8.6 ± 2.5 vs. 11.9 ± 3.7 days), mechanical ventilation durations (5.4 ± 2.1 vs. 9.1 ± 3.4 hours), times to ambulation (2.0 ± 0.8 vs. 3.4 ± 1.1 days), and oral feeding (1.8 ± 0.7 vs. 2.9 ± 1.0 days; all p<0.001). Myocardial infarction, arrhythmia, acute kidney injury, wound infection, reoperation, and 30-day mortality were numerically less frequent in Group E, but the between-group differences were not statistically significant.

Conclusion

Epidural analgesia was associated with lower observed composite morbidity, lower pain scores, and more favorable short-term recovery measures after open aortofemoral bypass. The retrospective, nonrandomized design and potential confounding by indication preclude causal conclusions. Prospective studies should evaluate comparative effectiveness, patient selection, and analgesia-related safety.

Categories: Cardiac/Thoracic/Vascular Surgery, Anesthesiology
Keywords: aortofemoral bypass, aortoiliac occlusive disease, epidural analgesia, outcome analysis, postoperative complications

Introduction

Aortoiliac occlusive disease is a manifestation of peripheral arterial disease that can cause intermittent claudication, functional limitation, ischemic rest pain, and tissue loss [1]. Treatment selection depends on the anatomical extent of disease, clinical severity, patient comorbidities, and the feasibility of endovascular

or open reconstruction [2]. Despite advances in endovascular treatment, open aortofemoral bypass remains an established revascularization option for selected patients with extensive aortoiliac disease [3].

Open aortofemoral bypass involves major abdominal and vascular surgery and may be followed by substantial postoperative pain and cardiopulmonary morbidity. Effective analgesia is important because pain can impair deep breathing, coughing, and mobilization, while systemic opioids may contribute to sedation and respiratory depression. The choice of analgesic technique is therefore relevant to postoperative respiratory function, functional recovery, and resource utilization [4].

Thoracic epidural analgesia is an established option for pain management following major open abdominal surgery [5]. A Cochrane review of trials involving elective open abdominal aortic surgery found that epidural analgesia improved postoperative pain control and was associated with reductions in selected outcomes, including postoperative respiratory failure and intensive care unit (ICU) stay, although a reduction in 30-day mortality was not demonstrated [6]. Although evidence supports the use of epidural analgesia in open abdominal aortic surgery, its effectiveness in patients undergoing aortofemoral bypass for aortoiliac occlusive disease warrants specific evaluation because differences in underlying vascular pathology, clinical presentation, and perioperative risk profiles may influence postoperative outcomes [7]. Moreover, evidence from enhanced recovery settings suggests that the advantages of epidural analgesia over alternative analgesic strategies may vary according to the surgical population and perioperative protocol [8].

The purpose of the present study was not to establish whether epidural analgesia is generally effective in open aortic surgery, a question already addressed by previous studies. Rather, it was to examine the association between the documented use of epidural analgesia and short-term postoperative outcomes in a specific cohort undergoing open aortofemoral bypass for aortoiliac occlusive disease at a tertiary care center in Bangladesh. This setting-specific comparison may provide useful observational data for local perioperative practice, while recognizing that treatment selection was not randomized.

The primary objective was to compare 30-day composite postoperative morbidity between patients receiving general anesthesia with thoracic epidural analgesia and those receiving general anesthesia with systemic opioid analgesia alone. Secondary objectives were to compare postoperative pain scores, pulmonary complications, mechanical ventilation duration, time to ambulation, time to oral feeding, ICU stay, hospital stay, and 30-day mortality. An exploratory analysis was also undertaken to examine associations between selected clinical variables and composite morbidity. We hypothesized that epidural analgesia would be associated with lower observed postoperative morbidity and more favorable early recovery outcomes, without assuming a causal treatment effect.

Materials And Methods

Study design and setting

This retrospective comparative observational study was conducted in the Department of Anaesthesia, Analgesia and Intensive Care Medicine, Bangladesh Medical University, Bangladesh. Medical records of patients undergoing elective open aortofemoral bypass for aortoiliac occlusive disease between January 2021 and December 2024 were reviewed. A total of 120 consecutive eligible patients were included based on the prespecified eligibility criteria.

Because the study used existing clinical records, analgesic treatment was not assigned by the investigators. Randomization was not performed because the study was retrospective and designed to compare outcomes following analgesic techniques already used in clinical practice.

Eligibility criteria

Patients aged 18 years or older, with aortoiliac occlusive disease confirmed by computed tomography angiography, who underwent elective open aortofemoral bypass, and had an American Society of Anesthesiologists (ASA) physical status of II-IV [9] were included. Patients undergoing emergency surgery, those with ruptured aneurysm, coagulopathy, severe spinal deformity, infection at the epidural insertion site, or chronic opioid dependence, and those with incomplete medical records were excluded.

Group classification and potential confounding

Patients were classified according to the analgesic technique documented in their medical records. Group E comprised patients who received general anesthesia with thoracic epidural analgesia (n=60), whereas Group G comprised patients who received general anesthesia with systemic opioid analgesia alone (n=60).

The decision to use epidural analgesia was not randomized. Potential determinants of treatment allocation included patient characteristics, suitability for neuraxial analgesia, antiplatelet or anticoagulant treatment, anesthesiologist and surgeon preference, and institutional practice. Treatment allocation was non-randomized and may have been influenced by clinical judgment and patient characteristics. Therefore, differences in outcomes may reflect selection bias and residual confounding, which cannot be excluded by

similar baseline p-values. Consequently, differences in outcomes between groups may reflect both the analgesic technique and underlying differences in patient selection or perioperative management. Similar baseline p-values do not establish equivalence between the groups or exclude residual confounding.

Anesthetic and surgical management

In Group E, a thoracic epidural catheter was inserted at the T8-T10 level before induction of general anesthesia. After confirmation of appropriate catheter placement, an epidural test dose was administered according to institutional practice. Epidural bupivacaine 0.125% combined with fentanyl 2 µg/mL was used for postoperative analgesia. The solution was administered via continuous epidural infusion, with the rate individualized according to pain relief, sensory block, and hemodynamic status. Analgesia was continued for up to 48 hours postoperatively, with regular assessment of pain scores, blood pressure, heart rate, motor function, sensory level, respiratory status, and signs of local anesthetic or opioid toxicity. The infusion was reduced or discontinued if clinically significant hypotension, excessive motor block, respiratory depression, or other serious adverse effects occurred. Epidural catheter removal was coordinated with anticoagulation management to minimize the risk of neuraxial hematoma.

Group G received intravenous opioid-based analgesia with fentanyl and morphine according to institutional protocols. Postoperative pain was assessed regularly, and rescue analgesia was administered when pain relief was inadequate. Rescue medications included pethidine (1 mg/kg), intravenous ketorolac (3 mg), or rectal diclofenac (50 mg), according to clinical assessment and institutional protocol. Patients were monitored for pain relief, analgesic requirements, and potential adverse effects.

All patients underwent transperitoneal open aortofemoral bypass using Dacron grafts under systemic heparinization. Intravenous unfractionated heparin was administered at 80-100 IU/kg before aortic clamping, followed by a maintenance infusion of 20 IU/kg/h for 48 hours, with activated partial thromboplastin time monitoring. Antiplatelet therapy was withheld preoperatively (aspirin for five days and clopidogrel for seven days) and restarted 48 hours postoperatively, subject to hemostatic stability. Protamine reversal, if used, and postoperative thromboprophylaxis were managed according to the operative records and institutional protocol.

Study variables and outcomes

Demographic variables included age, sex, smoking history, diabetes mellitus, hypertension, coronary artery disease, chronic obstructive pulmonary disease (COPD), and ASA physical status. Operative variables included operative duration, aortic cross-clamp time, estimated blood loss, and intraoperative transfusion.

The primary outcome was 30-day composite postoperative morbidity. The composite outcome included all postoperative complications recorded in the study dataset within 30 days of surgery. Each patient was counted only once in the composite outcome, regardless of the number of complications experienced.

Pulmonary complications were defined as postoperative respiratory events documented in the medical record, including pneumonia, respiratory failure, reintubation, and prolonged ventilatory support, where recorded and assessed during the study period.

Secondary outcomes included the 24-hour postoperative visual analog scale (VAS) pain score [10], duration of mechanical ventilation, ICU stay, hospital stay, time to ambulation, time to initiation of oral feeding, individual postoperative complications, and 30-day mortality. Postoperative pain was assessed using the VAS at the time points documented in the study records. Pain assessments were performed by the responsible clinical team using the available assessment procedures. Thirty-day postoperative outcomes were ascertained from documented clinical follow-up and available medical records.

Statistical analysis

Data were analyzed using IBM SPSS Statistics, version 26 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as means ± standard deviations (SDs), and categorical variables as frequencies and percentages. Continuous outcomes were compared using independent-samples t-tests when their distribution and variance assumptions were appropriate. Categorical outcomes were compared using Pearson's chi-square test or Fisher's exact test, as appropriate, with exact testing preferred for sparse contingency tables. A two-sided p-value below 0.05 was considered statistically significant.

Ethical considerations

The study protocol received approval from the Institutional Ethical Review Committee (ERC) of Bangladesh Medical University, Dhaka, Bangladesh (memo no. ERC-BMU/ECC/176/2021). Written informed consent was obtained from all participants in accordance with the approved protocol. Confidentiality was ensured by using coded records to protect participants' identities, and all study procedures adhered to the applicable ethical guidelines for research involving human subjects.

Results

A total of 120 patients were included in the study, with 60 patients in each group. The mean age was 62.1 ± 8.4 years in Group E and 63.8 ± 7.9 years in Group G (t=-1.14, p=0.28). A total of 50 (83.3%) patients in Group E and 52 (86.7%) patients in Group G (χ^2=0.26, p=0.60) were male. No statistically significant between-group differences were observed in smoking history (χ^2=0.33, p=0.56), diabetes mellitus (χ^2=0.31, p=0.57), hypertension (χ^2=0.14, p=0.70), coronary artery disease (χ^2=0.17, p=0.68), COPD (χ^2=0.22, p=0.64), or ASA III/IV classification (χ^2=0.16, p=0.68) (Table *1*).

Variable	Group E (n=60)	Group G (n=60)	Test statistic	p-value
Age (years)	62.1 ± 8.4	63.8 ± 7.9	t=-1.14	0.28
Male sex, n (%)	50 (83.3)	52 (86.7)	χ^2=0.26	0.60
Smoking history, n (%)	38 (63.3)	41 (68.3)	χ^2=0.33	0.56
Diabetes mellitus, n (%)	24 (40.0)	27 (45.0)	χ^2=0.31	0.57
Hypertension, n (%)	37 (61.7)	39 (65.0)	χ^2=0.14	0.70
Coronary artery disease, n (%)	15 (25.0)	17 (28.3)	χ^2=0.17	0.68
COPD, n (%)	10 (16.7)	12 (20.0)	χ^2=0.22	0.64
ASA III/IV, n (%)	42 (70.0)	44 (73.3)	χ^2=0.16	0.68

TABLE 1: Baseline demographic and clinical characteristics of patients in the epidural and general anesthesia groups

Data are presented as means ± standard deviations (SDs) or numbers (%), as appropriate. An independent-samples t-test was used for comparison of continuous variables, and Pearson's chi-square (χ^2) test was used for categorical variables. A p-value <0.05 was considered statistically significant.

Group E, general anesthesia with thoracic epidural analgesia; Group G, general anesthesia with systemic opioid analgesia alone; COPD, chronic obstructive pulmonary disease; ASA, American Society of Anesthesiologists physical status classification

Mean operative duration was 4.6 ± 0.9 hours in Group E and 4.8 ± 1.0 hours in Group G (t=-1.15, p=0.252). Aortic cross-clamp time was also comparable between the groups (54.2 ± 11.5 vs. 56.7 ± 12.1 minutes; t=-1.16, p=0.25). Estimated blood loss was 720 ± 180 mL in Group E and 770 ± 210 mL in Group G (t=-1.40, p=0.16). Intraoperative transfusion was required in 18 (30.0%) patients in Group E and 21 (35.0%) in Group G (χ^2=0.34, p=0.56).

The mean VAS pain score at 24 hours was significantly lower in Group E than in Group G (3.2 ± 1.1 vs. 5.9 ± 1.5; t=-11.24, p<0.001). ICU stay was shorter in Group E (2.3 ± 0.9 vs. 3.7 ± 1.4 days; t=-6.52, p<0.001), as was overall hospital stay (8.6 ± 2.5 vs. 11.9 ± 3.7 days; t=-5.72, p<0.001). Time to ambulation was 2.0 ± 0.8 days in Group E compared with 3.4 ± 1.1 days in Group G (t=-7.97, p<0.001), while time to initiation of oral feeding was 1.8 ± 0.7 versus 2.9 ± 1.0 days, respectively (t=-6.98, p<0.001). Mechanical ventilation duration was also shorter in Group E than in Group G (5.4 ± 2.1 vs. 9.1 ± 3.4 hours; t=-7.17, p<0.001) (Table *2*).

Variable/outcome	Group E (n=60)	Group G (n=60)	Test statistic	p-value
Intraoperative characteristics				
Operative duration (hours), mean ± SD	4.6 ± 0.9	4.8 ± 1.0	t=−1.15	0.252
Aortic cross-clamp time (minutes), mean ± SD	54.2 ± 11.5	56.7 ± 12.1	t=−1.16	0.25
Estimated blood loss (mL), mean ± SD	720 ± 180	770 ± 210	t=−1.40	0.16
Intraoperative transfusion, n (%)	18 (30.0)	21 (35.0)	χ^2=0.34	0.56
Early postoperative outcomes				
VAS pain score at 24 hours, mean ± SD	3.2 ± 1.1	5.9 ± 1.5	t=−11.24	<0.001
ICU stay (days), mean ± SD	2.3 ± 0.9	3.7 ± 1.4	t=−6.52	<0.001
Hospital stay (days), mean ± SD	8.6 ± 2.5	11.9 ± 3.7	t=−5.72	<0.001
Time to ambulation (days), mean ± SD	2.0 ± 0.8	3.4 ± 1.1	t=−7.97	<0.001
Time to oral feeding (days), mean ± SD	1.8 ± 0.7	2.9 ± 1.0	t=−6.98	<0.001
Mechanical ventilation (hours), mean ± SD	5.4 ± 2.1	9.1 ± 3.4	t=−7.17	<0.001

TABLE 2: Intraoperative characteristics and early postoperative outcomes in the epidural and general anesthesia groups

Data are presented as means ± standard deviations (SDs) or numbers (%), as appropriate. An independent-samples t-test was used for continuous variables, and Pearson's chi-square (χ^2) test was used for categorical variables. A p-value <0.05 was considered statistically significant.

Group E, general anesthesia with thoracic epidural analgesia; Group G, general anesthesia with systemic opioid analgesia alone; VAS, visual analog scale; ICU, intensive care unit

Pulmonary complications occurred in 7 (11.7%) patients in Group E and 17 (28.3%) patients in Group G (χ^2=5.21, p=0.024). The reported rates of myocardial infarction, arrhythmia, acute kidney injury, wound infection, reoperation, and 30-day mortality were numerically lower in Group E; however, none of these differences reached statistical significance. Myocardial infarction occurred in 2 (3.3%) versus 6 (10.0%) patients (χ^2=2.14, p=0.272), arrhythmia in 5 (8.3%) versus 11 (18.3%) (χ^2=2.60, p=0.107), acute kidney injury in 4 (6.7%) versus 9 (15.0%) (χ^2=2.16, p=0.142), wound infection in 3 (5.0%) versus 7 (11.7%) (χ^2=1.75, p=0.322), and reoperation in 1 (1.7%) versus 3 (5.0%) patients (χ^2=1.03, p=0.619). Thirty-day mortality was 1 (1.7%) in Group E and 3 (5.0%) in Group G (χ^2=1.03, p=0.619). Composite morbidity occurred significantly less frequently in Group E than in Group G, affecting 14 (23.3%) and 30 (50.0%) patients, respectively (χ^2=9.19, p=0.002) (Table *3*).

Complication	Group E, n (%)	Group G, n (%)	Test statistic	p-value
Pulmonary complications	7 (11.7)	17 (28.3)	χ^2=5.21	0.024
Myocardial infarction	2 (3.3)	6 (10.0)	Fisher's exact	0.272
Arrhythmia	5 (8.3)	11 (18.3)	χ^2=2.60	0.107
Acute kidney injury	4 (6.7)	9 (15.0)	χ^2=2.16	0.142
Wound infection	3 (5.0)	7 (11.7)	Fisher's exact	0.322
Reoperation	1 (1.7)	3 (5.0)	Fisher's exact	0.619
30-day mortality	1 (1.7)	3 (5.0)	Fisher's exact	0.619
Composite morbidity	14 (23.3)	30 (50.0)	χ^2=9.19	0.002

TABLE 3: Postoperative complications and 30-day mortality in the epidural and general anesthesia groups

Data are presented as numbers (%). Pulmonary complications refer to clinically documented postoperative respiratory complications. Composite morbidity was defined as the occurrence of at least one predefined postoperative complication per patient. Pearson's chi-square (χ^2) test was used for comparisons of categorical variables when appropriate, and Fisher's exact test was used for outcomes with small expected cell counts. All tests were two-sided, and a p-value <0.05 was considered statistically significant.

Group E, general anesthesia with thoracic epidural analgesia; Group G, general anesthesia with systemic opioid analgesia alone

Discussion

This retrospective comparative study examined the association between thoracic epidural analgesia and short-term outcomes after elective open aortofemoral bypass for aortoiliac occlusive disease. Patients receiving epidural analgesia had lower recorded postoperative pain scores, fewer pulmonary complications, shorter reported mechanical ventilation duration, earlier ambulation and oral feeding, and shorter ICU and hospital stays. Composite postoperative morbidity was also less frequent in this group. These findings are clinically relevant but should be interpreted as observational associations rather than evidence of a causal treatment effect.

The use of epidural analgesia in open aortic surgery has been investigated in randomized controlled trials [11,12]. The rationale for the present study was therefore not to establish the general efficacy of epidural analgesia, but to examine its association with recovery following open aortofemoral bypass performed for occlusive disease in a specific tertiary-care setting. Evidence from abdominal aortic aneurysm repair may not fully represent patients with aortoiliac occlusive disease, whose clinical severity, anatomical characteristics, and comorbidity profiles may differ [13].

The observed difference in 24-hour VAS pain scores is consistent with the findings of the Cochrane review by Nishimori et al., which reported improved pain relief with epidural analgesia compared with systemic opioid-based analgesia in elective abdominal aortic surgery [14]. However, evidence from other surgical populations has been less consistent regarding overall morbidity and length of hospital stay when epidural analgesia is compared with alternative techniques within enhanced recovery pathways [15]. The results of the present study should therefore be interpreted alongside the broader evidence rather than as confirmation that epidural analgesia is universally superior.

Effective thoracic epidural analgesia may reduce pain during inspiration and coughing, facilitating deep breathing, secretion clearance, and participation in respiratory physiotherapy [16]. Improved analgesia may also make transfers and early mobilization more tolerable. In addition, reduced systemic opioid requirements could potentially limit sedation and opioid-related respiratory depression [17]. These mechanisms provide a plausible explanation for the lower observed pain scores and pulmonary complication rates in Group E.

Nevertheless, the present study did not establish that these mechanisms mediated the observed differences. Data on total postoperative opioid consumption, respiratory physiotherapy, fluid management, and adherence to enhanced recovery practices were not presented. Differences in these factors, if present, may have contributed to the group differences in recovery.

Pulmonary complications were documented in 11.7% of patients receiving epidural analgesia and 28.3% of those receiving systemic opioid analgesia alone. Although this difference was statistically significant in the

reported analysis, the absence of random treatment allocation limits causal interpretation. Patient selection, baseline respiratory status, operative complexity, and postoperative care may have influenced both treatment allocation and pulmonary outcomes [18].

Composite morbidity was recorded in 23.3% of Group E and 50.0% of Group G. The composite outcome represented overall postoperative complication burden and included the individual complications documented in the study dataset. Each patient was counted only once, even when multiple complications occurred. The observed difference should be interpreted in the context of the clinical significance of the component events and the limitations of the outcome definitions and statistical analyses.

Epidural analgesia may be associated with hypotension, urinary retention, technical failure, and other neuraxial complications. In vascular surgery, particular attention is required when systemic heparinization and perioperative antiplatelet or anticoagulant treatment are used because of the potential consequences of neuraxial bleeding [19,20]. The benefits of analgesia must therefore be balanced against individual contraindications and procedural risks.

The findings suggest that epidural analgesia may be a useful component of multimodal perioperative analgesia for appropriately selected patients undergoing open aortofemoral bypass. However, they do not establish that epidural analgesia should be preferred for all patients. Treatment decisions should account for neuraxial contraindications, anticoagulation requirements, hemodynamic status, local expertise, and the availability of alternative analgesic strategies [21].

This study has several limitations. First, the retrospective, nonrandomized design creates a risk of confounding by indication and residual confounding. Second, the reasons for selecting epidural or systemic opioid analgesia require further clarification, and the available data do not establish that the groups were clinically equivalent. Third, the study was conducted at a single center and included a relatively small sample. Fourth, only 44 patients experienced composite morbidity, limiting the reliability of a six-predictor logistic regression model. Fifth, the operational definitions of pulmonary complications and composite morbidity, the standardization of VAS assessments, and the completeness of 30-day outcome ascertainment require clearer documentation. Finally, detailed comparative information on opioid consumption, epidural-related adverse effects, anatomical lesion complexity, clinical limb severity, and perioperative management was not presented. These limitations should be considered when interpreting the observed associations.

Because this study was conducted at a single center, its findings may not be directly generalizable to institutions with different patient populations, surgical techniques, analgesic protocols, or enhanced recovery pathways. The results are best viewed as setting-specific observational evidence that may inform future comparative research.

Conclusions

Thoracic epidural analgesia was associated with lower postoperative pain scores, fewer recorded pulmonary complications, and more favorable short-term recovery outcomes following open aortofemoral bypass for aortoiliac occlusive disease. Given the retrospective, nonrandomized design, these findings should be interpreted as associations rather than causal effects. Prospective comparative studies are warranted to evaluate the effectiveness, patient selection, and safety of epidural analgesia in this specific surgical population.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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Disclosures

Human subjects: Informed consent for treatment and open access publication was obtained or waived by all participants in this study. Ethical Review Committee of Bangladesh Medical University issued approval ERC-BMU/ECC/176/2021. **Animal subjects:** All authors have confirmed that this study did not involve animal subjects or tissue. **Conflicts of interest:** In compliance with the ICMJE uniform disclosure form, all authors declare the following: **Payment/services info:** All authors have declared that no financial support was received from any organization for the submitted work. **Financial relationships:** All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work. **Other relationships:** All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

Acknowledgements

ChatGPT (OpenAI, San Francisco, USA) was used to assist with language editing and manuscript refinement. The authors reviewed and verified the final content and take full responsibility for the accuracy and integrity of the manuscript.

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