REVIEW REPORT

Title: Early outcomes after intra-cardiac repair for late-presenting tetralogy of Fallot

Authors: Sonjoy Biswas, Md. Aminullah

Round 1

Reviewer A: Taskina Mosleh, **ORCID:** 0009-0008-9519-8000, **COI:** None, **AI disclosure:** None

1. Comment Completeness and accuracy of the Abstract.

The abstract is well written and clearly divided into sections. However, the following issues need to be addressed.
-Method section should include sampling technique, exclusion criteria, follow up method.
-line 29, in result section major disparity of data from table1 age range (2-26 vs 5-10)

Response: The method section has been included with sampling technique, exclusion criteria and follow-up methods (Lines 25-31). Range has been replaced with (inter-quartile range: 5–10), (Line 29).

2. Comment Clarity and appropriateness of the Objective(s).

The objective appears to be diffuse, includes several aims together. Primary and secondary objectives need to be clearly stated.

Response: The changes in the objective has been done: "Our study aims to provide a comprehensive understanding of post-operative complications, primarily RV dysfunction, during both the immediate postoperative period and follow-up among the late presenters of TOF. We also aim to evaluate the effect of transannular patch (TAP), valve-sparing RVOT patch augmentation or infundibular resection on early outcome of the patient with late presentation. This approach ensures that our findings are reliable and are consistent with real-world surgical setting." (Lines 77-81:).

3. Comment Clarity of the rationale for conducting the study is given in the Introduction section.

Background of this study is informative. But the authors do not clearly specify what evidence is lacking,
• Please clarify why previous studies are insufficient. Please search for more local evidence.
• What new contribution this study provides
• Description of surgical techniques in the introduction can be shortened to keep focus on the major objective of the study.

Response: The local evidences are insufficient due to lack of publications.
"In Bangladesh, diagnosis of TOF is often delayed because of limited number of pediatric cardiology and pediatric cardiac surgery departments. This study is a quasi-experimental study featuring surgical outcomes of TOF in children with late presentation operated at Bangladesh Medical University (BMU)." (Lines 74-76)
Intra-cardiac repair of TOF has replaced palliative shunt operations. This is a curative one. Thus, the steps are depicted here. The main surgical steps written here as short as possible.

4. Comment The Methods are described in sufficient details so that the study can be reproduced. Whether ethical concerns have been well described.

- The sampling technique, including sample size calculation and study power, should be clearly described in the method section. Please specify the age range of study subjects, as in discussion line-164 states, "This study included both children and adults."
- The absence of a control group weakens the strength of the findings.
- Baseline disease severity at enrollment is not reported, and the potential for selection bias, along with methods used to address it, should be clearly stated.
- The echocardiographic grading criteria used for severity assessment should also be specified.
- The ethical approval statement is insufficient; it should clearly state whether IRB approval was obtained, whether informed consent was taken for the procedure and/or study participation, and whether assent was obtained for participants aged over 10 years.
- As stated in line 248, "Ethical approval was not required," creates a major ethical issue in an experimental study design.

Response:

- The methodology is described in a broader term (Lines 84-100).
- The median age 6 years with IQR: 5–10 as depicted in Table 1.

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- "All the pre-operative, immediate post-operative and follow-up echocardiography were done by the same cardiologist at the Department of Pediatric Cardiology, BMU in the same setting. Pre-operative CT-angiograms were also done and reported in the same setting." Severity of TOF is described in echocardiography. But, in reports they are not classified as mild, moderate or so (Lines 90-92).
- As the same cardiologist has done all the echocardiogram, then there is less chance of bias.
- " The pre-operative evaluations, surgical procedure, post-operative managements and follow-up investigations were done as part of routine works as done for every patient in the Department irrespective of diagnosis. No separate intervention was done for this study. All the patients and patients' legal guardian or next of kin gave their informed consent prior undergoing surgery. All data and patient information were collected routinely and handled confidentially" (Line 253-257).

5. Comment Clarity and appropriateness of the Design to achieve the objective(s).

The design is not strong enough to support causal interpretations regarding the comparative effectiveness of different surgical techniques, as there was no randomization or control for confounding factors.

Response: As it is a quasi-experimental study, there is no randomization, no control group; thus, the study designs describe.

6. Comment Appropriate and thorough description of the Statistical methods.

The study aims to evaluate the effects of different surgical procedures, but only simple descriptive statistics were used. No comparative or inferential statistical analysis was done. Important factors like age, severity of pulmonary stenosis, presence of MAPCAs, and bypass time were not adjusted. Using regression analysis would make the results more reliable.

Response: Severity of pulmonary stenosis, presence of MAPCAs is a categorical variable. So, there is no scope for regression analysis. In this study, due to lack of any control group, no comparison was done

7. Comment Quality, clarity and appropriateness of the Table(s).

Table 1, Mean ± SD may be more appropriate for normally distributed variables. (age, BMI etc)
Column heading "Result" seems vague, it can be replaced by mean, median or percentage.
Table 3,check calculation for "Moderate to severe right ventricular dysfunction = 7 (11.3%)"
As (7/60 = 11.7%, not 11.3%), include p-values in tables

Response: As all the data are skewed, so non-parametric central tendencies are described; i.e. median (IQR). Necessary corrections in Table 3 have been done

8. Comment Major redundancy between text and tables/figures in the Results section.

- Most findings are described narratively without presenting actual numerical results. Important information is missing. The results section should provide numerical data with appropriate statistical summaries.
- The Results section includes many procedural and methodological descriptions that belong in the Methods section rather than Results. better fit in the method section (Line 132-136 and 138-153).
- There is an inconsistency in the reported follow-up numbers. As per the manuscript, there are 5 deaths and 52 survivors (5+52=57). But the total enrolled patient were 60. Please clarify the discrepancy and provide a clear participant flow (e.g., a flow diagram) to ensure transparency.
- In result section major disparity of data from table-1 age range (2-26 vs 5-10) (Line 29).

Response: "Fifty-two patients came for follow-up". Thus 3 patients did not come for follow up after 90 days. Five patients died peri-operatively. Table 1, age is described as median (IQR): 6(5 – 10) (Lines 29, 36-37 and 157).

9. Comment Pertinence of the Discussion section whether it justify the main message of the manuscript without repeating the results.

The discussion section mainly describes findings without deeper clinical interpretation
• Why postoperative RV dysfunction was high?
• Why does mortality occur predominantly in the transannular patch group?
• Possible influence of delayed presentation.
• Role of MAPCAs, bypass time, or preoperative severity on outcomes. These findings should be discussed

Response: "Patients with intra-cardiac repair may experience complications including right ventricular failure, arrhythmias, severe pulmonary regurgitation and even sudden cardiac death later in life. The patients with severely stenosed pulmonary vale trans-annular patch augmentation is done following destruction of pulmonary valve which eventually causes free pulmonary regurgitation followed by right ventricular dysfunction" (Lines 213-217).

Higher prevalence of MAPCA is seen in the older patients which is also increased in size that is identified in CT-angiography. The older the patent, there are more chance of presence of MAPCAs both in number and size (Lines 186-188).

" Per-operative median Cardio-pulmonary bypass and ischemic time are 136 and 110 minutes respectively in this study which is a little higher than some of previous studies. The less the CPB or ischemic time, apparently less the adverse outcomes" (Lines 190-192).

10. Comment Whether Strength(s) and Limitation(s) are well described.

This article describes several strengths of the study including prospective followup. However, limitations section is insufficient and does not fully address several important methodological weaknesses of the study. (Absence of inferential statistical analysis, lack of adjustment for confounding variables, absence of a comparison/control group, potential selection bias etc)

Response: The strength of this study is that it is done prospectively throughout in the hospital under direct participation by the expert surgeon. The study's another advantage is an analysis of the outcomes of different surgical modalities thus aiding in successfully planning appropriate surgical management of TOF. Yet there is some limitations. A larger and substantial sample size for generalizing the study and further follow-ups would have strengthened the study (Lines 224-228).

11. Comment Whether the Conclusion of the manuscript is supported by the data.

with 8.3% mortality, this study concluded as "late surgery can yield acceptable early outcome". Please justify the "acceptable" term without comparison benchmarks.

Response: "The in-hospital mortality is 5 (8.3%). In the most of the previous studies, it is 1.8 to 8%". As the ideal time for intra-cardiac repair is infancy, so the older the patient, the chance of mortality is more. Previous references depict the same (Lines 209).

12. Comment Whether the manuscript is supported by appropriate and up-to-date References.
References 2 and 9 are same
References 16 and 18 are same
Reference 12 does not seem valid. It should be replaced with a valid reference

Response:

- Reference 9: Dłużniewska N, Podolec P, Skubera M, et al. Long-term follow-up in adults after tetralogy of Fallot repair. Cardiovascular Ultrasound. 2018 Oct;16(1):28. DOI: 10.1186/s12947-018-0146-7. PMID: 30373624; PMCID: PMC6206664.
- Reference 12: Nicholas T. Kuchoukos, Eugene H. Blackstone, Frank L. Hanley, James K. Kirklin, eds. Kiklin / Barratt-Boyes Cardiac Surgery. 4th eds. Elsvier Saunders, Philadelphia, PA;2013, pp 41.
- Reference 18: Peck D, Tretter J, Possner M, et al. Timing of Repair in Tetralogy of Fallot: Effects on Outcomes and Myocardial Health. Cardiology in Review. 2021 Mar-Apr 01;29(2):62-67. DOI: 10.1097/crd.0000000000000293. PMID: 31934899.

13. Comment Straightforward, clear, and logical Storytelling. The manuscript tells a logical story, but clarity and flow can be improved.

Response: As The clarity has been tried to be improved.

14. Comment Standard of English for publication. Scientific language is well written. Some linguistic corrections are required.

Response: Has been revised for improvement

Reviewer B: **Ferdousi Rahman,** **ORCID:** **0009-0004-0140-0695,** **COI:** **None,** **AI disclosure:** **None**

15. Comment Appropriateness of the Title.
The title can be revised as "Early outcomes following intra-cardiac repair of tetralogy of Fallot with late presentation."

Response: As the title is preferred consisting of two clauses thus the title is chosen: "Early outcomes following intra-cardiac repair of tetralogy of Fallot with late presentation: A quasi-experimental study"

16. Comment Clarity of the rationale for conducting the study is given in the Introduction section. The rationale should be more clarified (Lines 74, 75, 76, 77, 78).

Response: "In the developing world, most of the patients of TOF are diagnosed and treated in later stages of their life, usually after the age of one year. There is still a burden of uncorrected TOF patients reaching adulthood and it is common for late presentation of TOF patients to a hospital compared to that of developed countries. Surgical repair of TOF in older children is associated with more operative complications e.g. bleeding, right ventricular dysfunction, low cardiac output syndrome, arrhythmias and even mortality (Lines 69-81).
In Bangladesh, diagnosis of TOF is often delayed because of limited number of pediatric cardiology and pediatric cardiac surgery departments. This study is a quasi-experimental study featuring surgical outcomes of TOF in children with late presentation operated at Bangladesh Medical University (BMU). Our study aims to provide a comprehensive understanding of postoperative complications, primarily RV dysfunction, during both the immediate postoperative period and follow-up among the late presenters of TOF. We also aim to evaluate the effect of transannular patch (TAP), valve-sparing RVOT patch augmentation or infundibular resection on early outcome of the patient with late presentation. This approach ensures that our findings are reliable and are consistent with real-world surgical setting."

17. Comment Clarity and appropriateness of the Design to achieve the objective(s).
Quasi experimental study is appropriate for this study.

Response: "This is a quasi-experimental study involving 60 patients with TOF undergoing intra-cardiac repair in BMU from January to December 2025" (Lines 85).

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Reviewer D: Mohammad Saief Uddin, **ORCID:** 0009-0007-0023-6725, **COI:** None, **AI disclosure:** None

18. Comment Appropriateness of the Title.

It is an experimental study but there's no comparison group in the title. Title should include to whom the early outcomes in patient with late presentation are comparing.

Response: This is a quasi-experimental study. It has no control group and no randomization.

19. Comment Completeness and accuracy of the Abstract.

Grammar and punctuation mark (double comma) should be avoided. In line 26, if the patient underwent surgery up to March'26 then how the 90 day's follow up given? Which one was last day of surgery? In line 33, there's no mention of missing follow up count. In line 36, what is the meaning of acceptable? In abstract, your conclusion and your findings are contradictory! If earlier repair is good for long term then how late repair acceptable? Abstract is one sided and results are not clearly defined (Line 22).

Response:

- Done. "However, most of the patients present later in life in Bangladesh" (Lines 22-23).
- Correction done. "This quasi-experimental study included 60 TOF patients who underwent intra-cardiac repair at our facility between January and December 2025" (Lines 25-26).
- The last patient underwent surgery in December, 2025. The last patient followed up in March, 2026.
- "Fifty-two patients came for follow-up" (Line 36).
- "… most of the patients present later in life in Bangladesh." As the patients come for treatment later in life, then we have to treat them as soon as possible (Line 22).
- "In the developing world, most of the patients of TOF are diagnosed and treated in later stages of their life, usually after the age of one year. There is still a burden of uncorrected TOF patients reaching adulthood and it is common for late presentation of TOF patients to a hospital compared to that of developed countries" (Lines 69-72).

20. Comment Clarity and appropriateness of the Objective(s).

In line 50 and 51 there's no reference is given. In introduction, is it necessary of giving description of how surgery is being performed? (Line 60 to 63). It is said quasi-experimental but to whom it is comparing? (Line 72, 73). In looks like observational study. Rationality is not clear in introduction as an experimental study (Lines 74, 75, 76).

Response: Cited reference: "Waqar T, Riaz MU, Mahar T. Tetralogy of Fallot repair in patients presenting after Infancy: A single surgeon experience. Pak J Med Sci. 2017;33(4):984-987. doi: https://doi.org/10.12669/pjms.334.12891" (Lines 50-51).

This study has no control, no randomization; but, an intervention (intra-cardiac repair of TOF) is present. Thus, it is a quasi-experimental study.

21. Comment Clarity of the rationale for conducting the study is given in the Introduction section.

Again confused! Is it observational or experimental? If experimental then to whom it is compared? Is it necessary to mention formula of BSA and McGoon's ratio and give reference in study design (Line 89, 90, 91, 92, 93 and 94)? Isn't it established fact? Study design should include what and how it is intended to be shown. In line 111, what types of abnormalities corrected? In ethical consideration, is there formatted permission of IRB? Did they give permission to do this experiment?

Response: Mentioned earlier, it is a quasi-experimental study.

Yes, this should be clarified, as it has an impact on selection of the sample and they are formulated and not produced straight-forward.

- Study design has been revised and made more detailed (Lines 84-11).
- " At the ICU, the patient's ventilation time, inotropic support and ICU stay were recorded. Cardio-respiratory and renal functions were monitored. Abnormalities were noted and treated accordingly." Is there any abnormality present in ventilation time, inotropic support, ICU stay, cardio-respiratory and renal functions (Line 117).
- "All the pre-operative evaluations, surgical procedure and post-operative investigations were done as part of routine works as done for every patient in the Department irrespective of diagnosis." Thus, all the data are recorded in the Department. No separate intervention was done for this study (Lines 126).

22. Comment The Methods are described in sufficient details so that the study can be reproduced. Whether ethical concerns have been

Response: "…patients were pre-operatively evaluated clinically and radiologically with echocardiography and CT-angiography. We observed the early outcomes during the immediate postoperative period. They were followed-up clinically and with an echocardiography after ninety days. All the pre-operative, immediate post-operative and follow-up echocardiography were done by the same cardiologist at the Department of Pediatric Cardiology, BMU in the same setting. Pre-operative CT-angiograms were also done and reported in the same setting. Patients with TOF with discontinuous pulmonary arteries, pulmonary atresia, atrio-ventricular septal defects, absent pulmonary valve syndrome, with a McGoon's ratio less than 1.3

23. Comment Appropriate and thorough description of the Statistical methods.

Statistical analysis was very short and inadequate. If it shows outcomes after intervention then where is multivariate logistic analysis. Were the confounders controlled appropriately? Here, only descriptive analysis is calculated.

Response: As there is no control group, hence, there is lack of analysis of the confounders. Further mid-term or long-term follow-up may contribute to more analysis.

24. Comment Quality, clarity and appropriateness of the Table(s).

There's unnecessary sign inside table 1 (Beside BSA & McGoon's ratio) and it says patient demographic and clinical variable but no clinically identifiable variable is seen except the variable requires investigations to detect. IQR and Number (%) column is nil or isn't appropriately placed. In table 2, what does it means? Is median (IQR) demonstrated according to types of surgery? Or just a description? If only description then how it is meaningful to the study and its design? Is logistic analysis done with other variables? Is this table indicates any significance of your study? In table 3, are they compared with types of surgery performed? Does only description carry any value?

Response:

- BSA and McGoon ratio depict patient's profile and they are formulated. So, clarification is given.
- BSA is important for calculation for establishment of cardio-pulmonary bypass during open-heart operation.
- Line 184: "McGoon's ratio of more than 1.3 and above is recommended for the adequacy of the size of pulmonary arteries for intra-cardiac repair."
- Number (%) is rightly placed; i.e. 14 (23.3)..every time '%' is not put in the bracket.
- It is not only description purpose. As, the patch augmentation describes the complexity of surgery, it definitely predicts the outcome.
- The variables described in Table 3, give a vivid picture of the peri-operative performance of the surgery and thus predicts outcome.

25. Comment Quality, clarity and appropriateness of the Figure(s), if any.

Figures 1 also show only description of the variables. Again confused! Is it descriptive study or experimental study? As like as table.

Response: It is a quasi-experimental study.

26. Comment Pertinence of the Discussion section whether it justify the main message of the manuscript without repeating the results. Repetition and recapitulations of results and methods found in discussion without any practical implications! Discussion should rewrite.

27. Comment Whether Strength(s) and Limitation(s) are well described. Limitations and strengths are not mentioned clearly.

Response: "The strength of this study is that it is done prospectively throughout in the hospital under direct participation by the expert surgeon. The study's another advantage is an analysis of the outcomes of different surgical modalities thus aiding in successfully planning appropriate surgical management of TOF. Yet there is much limitations. A larger and substantial sample size for generalizing the study and further follow-ups would have strengthened the study" (Lines 224-228).

28. Comment Whether the Conclusion of the manuscript is supported by the data. Conclusion is confusing.

Response: The conclusion mimics the key message: "This study demonstrates that intra-cardiac repair of late-presenting tetralogy of Fallot can achieve acceptable early outcomes, even beyond infancy. However, late repair was associated with pulmonary regurgitation and right ventricular dysfunction, particularly in patients requiring trans-annular patch augmentation, highlighting the long-term advantages of earlier surgical intervention."

29. Comment Straightforward, clear, and logical Storytelling. Storytelling is confusing

Response: Has been revised as much as possible

30. Comment Standard of English for publication. English grammar should simple, clear and appropriate.

Response: Has been revised as much as possible.

31. Comment Appropriateness of the Title.

The study called " quasi-experimental," but the methodology does not actually represent a quasi-experimental because there is no intervention or comparison group. In the present study, outcomes were only descriptively reported in a single cohort without analytical comparison, therefore, the methodology is more consistent with a prospective observational study. " The title is clinically relevant; however, slight revision may improve methodological accuracy and better highlight the late-presenting TOF population studied."

Response: The study is a quasy-experimental; as it has a definite intervention; i.e. intra-cardiac repair of TOF.
The title has two clauses. Hence, the title is: "Early outcomes following intra-cardiac repair of tetralogy of Fallot with late presentation: A quasi-experimental study."

32. Comment Completeness and accuracy of the Abstract.

" The abstract is generally informative and reflects the main findings of the study. Minor revisions in wording and clearer description of the study design may further strengthen the study. The manuscript may be strengthened by more detailed information regarding follow-up outcomes and statistical analysis."

Response: Has been revised accordingly as much as possible

33. Comment Clarity and appropriateness of the Objective(s).

The objective is clinically relevant but may be further clarified if stated "systematic analysis" instead of "systemic analysis". The objective may clearly specify evaluation of early postoperative outcomes and complications following intracardiac repair in late presenting TOF patients.

Response: "Our study aims to provide a comprehensive understanding of postoperative complications, primarily RV dysfunction, during both the immediate postoperative period and follow-up among the late presenters of TOF. We also aim to evaluate the effect of transannular patch (TAP), valve-sparing RVOT patch augmentation or infundibular resection on early outcome of the patient with late presentation. This approach ensures that our findings are reliable and are consistent with real-world surgical setting" (Lines 77-81).

34. Comment Clarity of the rationale for conducting the study is given in the Introduction section.

The rational is generally understandable and relevant for resource- limited settings. However, the introduction can be modified to clearly connect delayed diagnosis, late repair and expected postoperative complications with relevance to this study.

Response: Have been revised as much as possible

35. Comment The Methods are described in sufficient details so that the study can be reproduced. Whether ethical concerns have been well described.

The surgical procedure is described reasonably well. However, the methodology would benefit from inclusion of ethical approval details, including the approving committee and reference number, if applicable. All the data were collected in no time, is not appropriate for scientific writing. Better alternative writing may be " clinical and operative data were recorded in a standardized manner."

Response: Methodology, ethical statement and data collection procedure has been written in details. (Lines 84-101 and 256 -260).

36. Comment Clarity and appropriateness of the Design to achieve the objective(s).
The study design seems appropriate for evaluating early postoperative outcomes , however ,the methodology may be more accurately described as a prospective observational study.

Response: There is a clear intervention; i.e. intra-cardiac repair of TOF. So, it is a "quasi-experimental study"

37. Comment Appropriate and thorough description of the Statistical methods.
The statistical analysis is generally described adequately. But inclusion of slightly more detailed analytical methodology and subgroup comparisons may further strengthen the interpretation of the findings.

Response: Have been revised as much as possible accordingly.

38. Comment Quality, clarity and appropriateness of the Table(s).
The tables are generally understandable but require formative improvement. the relevance of selected p-values presented in Table 1 may be clarified further.

Response: As there is no control group, hence, further analysis is limited.

39. Comment Major redundancy between text and tables/figures in the Results section.
There is some redundancy between text and tables. The text may focus on key findings rather than duplicating table contents in result section.

Response: Have been revised as much as possible accordingly.

40. Comment Pertinence of the Discussion section whether it justify the main message of the manuscript without repeating the results.

The discussion is clinically relevant but descriptive and repetitive. Greater analytical interpretation needed regarding causes of mortality, RV disfunction, pulmonary regurgitation, and implication of delayed repair.

Response: "Patients with intra-cardiac repair may experience complications including right ventricular failure, arrhythmias, severe pulmonary regurgitation and even sudden cardiac death later in life. The patients with severely stenosed pulmonary valve, trans-annular patch augmentation is done following destruction of pulmonary valve which eventually causes free pulmonary regurgitation followed by right ventricular dysfunction. Yet, the long-term reward of early repair is not known as it has not been confirmed whether a trans-annular patch repair with monocusp valve reconstruction would benefit TOF patients in perioperative period compared to those without monocusp valve reconstruction. In the developed countries, intra-cardiac repair for TOF is usually done between three to six months. However, due to various reasons including delay in diagnosis, financial problems, higher mortality due to scarcity of skilled medical manpower in underdeveloped countries, that is not a usual practice" (Lines 214-223).

41. Comment Whether Strength(s) and Limitation(s) are well described.
The strength and limitations are stated briefly ,but need further elaboration of methodological considerations may further enhance the scientific balance of the manuscript.

Response: "The strength of this study is that it is done prospectively throughout in the hospital under direct participation by the expert surgeon. The study's another advantage is an analysis of the outcomes of different surgical modalities thus aiding in successfully planning appropriate surgical management of TOF. Yet there is some limitations. A larger and substantial sample size for generalizing the study and further follow-ups would have strengthened the study" (Lines 224-228).

42. Comment Whether the Conclusion of the manuscript is supported by the data.
The conclusion is not fully supported by the data. Conclusion may be more balanced and relevant.

Response: Have been revised as much as possible accordingly.

43. Comment Whether the manuscript is supported by appropriate and up-to-date References. Most references are recent and relevant. Some references are not optimally matched to the discussion and can be reviewed carefully for relevance.

Response: Three references are revised:

- Reference 9: Dłużniewska N, Podolec P, Skubera M, et al. Long-term follow-up in adults after tetralogy of Fallot repair. Cardiovascular Ultrasound. 2018 Oct;16(1):28. DOI: 10.1186/s12947-018-0146-7. PMID: 30373624; PMCID: PMC6206664.
- Reference 12: Nicholas T. Kuchoukos, Eugene H. Blackstone, Frank L. Hanley, James K. Kirklin, eds. Kiklin / Barratt-Boyes Cardiac Surgery. 4th eds. Elsvier Saunders, Philadelphia, PA;2013, pp 41.
- Reference 18: Peck D, Tretter J, Possner M, et al. Timing of Repair in Tetralogy of Fallot: Effects on Outcomes and Myocardial Health. Cardiology in Review. 2021 Mar-Apr 01;29(2):62-67. DOI: 10.1097/crd.0000000000000293. PMID: 31934899.

44. Comment Straightforward, clear, and logical Storytelling.
The manuscript follows a logical structure. Some paragraphs are difficult to follow, may be due to grammatical issues.

Response: Have been revised as much as possible accordingly.

45. Comment Standard of English for publication.
The manuscript requires some grammatical correction throughout the text.

Response: Have been revised as much as possible accordingly.

Round 2

Reviewer A: Taskina Mosleh, ORCID: 0009-0008-9519-8000, COI: None, AI disclosure: None

1. Comment Several concerns raised in the previous review were addressed in the rebuttal in a descriptive manner, but the necessary corrections have not been properly implemented in the revised manuscript.

Response: I have tried to make the corrections in my revised manuscript as per your suggestion.

2. Comment In abstract, the actual age range (minimum–maximum) should be clearly stated, especially because both children and adults were included in the study.

Response: It has been stated as, "The age of the patients ranged from 2 to 26 years. While, the median age was 6 years (inter-quartile range: 5–10)" (Lines 32-33).

3. Comment The study rationale is still weak. Although a lack of local data is mentioned, the introduction does not clearly explain the specific knowledge gap this study is addressing. In addition, the introduction still includes unnecessary technical details about surgical procedures, which should be removed or reduced to improve focus.

Response: The statement has been revised highlighting the necessity of the study. The knowledge gap has been mentioned as, "In Bangladesh, diagnosis of TOF is often delayed because of limited number of pediatric cardiology and pediatric cardiac surgery departments. In addition, studies about the management of TOF with late presentation are limited in our country" (Lines 70-80).

4. Comment Important methodological and ethical issues remain insufficiently addressed. Key details such as study power, exact age range, baseline disease severity, and echocardiographic grading criteria are still missing. Moreover, ethical approval details (Approval number with date) are not provided. Simply stating that the procedures were part of routine care is not sufficient for a clinical trial.

Response: As per suggestion of the Institutional Review Board (IRB), this study has been addressed as a "retrospective observational study", thus the methodology has been designed.

1. It has been stated as, "The age of the patients ranged from 2 to 26 years. While, the median age was 6 years (inter-quartile range: 5–10)" (Lines 144-145).
2. Although severity of TOF is not graded as mild, moderate or severe, yet, the clinical spectra of the disease depend on grading of RVOT-PA gradient.

3. as mild, moderate or severe, yet, the clinical spectra of the disease depend on grading of RVOT-PA gradient.
4. "Baseline disease severity was assessed by degree of right ventricular outflow obstruction (RVOTO). Criteria for classification of severity of RVOTO was as follows; (i) mild RVOTO: RVOT-PA pressure gradient 20-40 mmHg, (ii) moderate RVOTO: gradient 41-70 mmHg and (iii) severe RVOTO: gradient >70 mmHg" (Line 103-106 states).
4. "In this study, most of the patients presented with severe RVOT obstruction (median RVOT-PA gradient was 82 mmHg) as they presented lately and the disease process advanced in course of time." (Lines194-196).
5. Echocardiographic grading of pulmonary regurgitation (PR) was determined by Color Doppler jet width at RVOT as; (i) mild PR: < 25% of RVOT diameter, (ii) moderate PR: 25 – 50% of RVOT diameter and (iii) mild PR: > 50% of RVOT diameter" (Lines 107-109).
6. "Echocardiographic grading of right ventricular dysfunction was determined by Color Doppler with measurement of TAPSE (Tricuspid Annular Plane Systolic Excursion) in mm; (i) normal: > 17 mm, (ii) mild RV dysfunction: 13-16 mm, (iii) moderate RV dysfunction: 9-12 mm and (iv) severe RV dysfunction: < 12 mm" (Lines 110-113)
7. As this study is a retrospective observational study and the study is non-interventional, hence it is classified as typically "minimum risk". So, the institutional review board (IRB) waived the reviewing process. The reference No. is BMU/2026/5723(c); dated 09-06-2026 (The soft copy and the date of the waiver approval have been provided as an attachment) (Lines 301-303)

5. Comment The loss to follow-up of the remaining 3 patients has not been clearly explained and should be properly addressed.

Response: " During the follow-up period, one patient was reported to have died at home from an undetermined cause" (Lines 161-162). "Two patients were not followed up as communication was not possible" (Lines163-164).

6. Comment The explanation regarding statistical analysis is not satisfactory. Even without a control group, appropriate comparative statistical tests could still be used to assess associations between surgical techniques and outcomes. The current reliance only on descriptive statistics limits the strength and interpretability of the findings.

Response: As mentioned earlier this study has been designed as a "Retrospective observational study", thus, only the descriptive statistics are depicted and much analysis couldn't be made. Yet, if later, the "mid-term" outcome is sought for the same patients, then further analysis could have been possible.

Reviewer B: **Ferdousi Rahman,** **ORCID:** **0009-0004-0140-0695,** **COI:** **None,** **AI disclosure:** **None**

7. Comment Most of the responses are satisfactory. However, an experimental study (with or without a control arm) needs ethics approval. Ideally, it should have a control arm as the standard of care. If the study is on record review, the study design will be observational. In either case, it requires an IRB clearance.

Response: As per suggestion of the Institutional Review Board (IRB), this study has been re-addressed as a "retrospective observational study", thus the methodology has been designed.

As this study is a retrospective observational study and the study is non-interventional, hence it is classified as typically "minimum risk". So, the institutional review board (IRB) waived the reviewing process. The reference No. is BMU/2026/5723(c); dated 09-06-2026 (The soft copy and the date of the waiver approval have been provided as an attachment) (Lines 301-303).

Reviewer D: **Mohammad Saief Uddin,** **ORCID:** **0009-0007-0023-6725,** **COI:** **None,** **AI disclosure:** **None**

8. Comment The authors have addressed the reviewer comments satisfactorily, and the manuscript has improved substantially in clarity and presentation. The topic remains clinically relevant, and the revised version appears suitable for publication.

Response: I have tried further revision for the precision of the manuscript.

Responsible editor: **M Mostafa Zaman,** **ORCID:** **0000-0002-1736-1342**

9. Comment I suggest obtaining an ethics exemption/approval letter from the IRB Secretariat, as this is routine work for the Department.

Kindly submit the revised version, a point-by-point response, along with the ethics exemption letter. We shall remain flexible about the timeline, but expect to close the file within the next 30 days. Let us know if you need more time.

Response:

1. I applied for the waiver of ethical review from the IRB (as this was a routine work of the department). The honorable Chairman of the IRB went through my application and the protocol meticulously. The IRB designated the study to be a "Retrospective observational study". The IRB suggested me for making correction of the title as "Early outcomes following intra-cardiac repair of tetralogy of Fallot with late presentation: A retrospective observational study".
2. I have made the necessary revision of the manuscript and the exemption / waiver from the IRB review was approved. The reference No. is BMU/2026/5723(c); dated 09-06-2026.
3. I have just submitted revised version of my manuscript, a point-by-point response along with the ethics exemption letter as attached files here within the time limit.

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