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International Journal of Advanced Research

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REVIEWER'S REPORT

Manuscript No.: IJAR-58277

Title: AN OBSERVATIONAL STUDY TO ESTIMATE THE PREVALENCE OF CONGENITAL HYPOTHYROIDISM IN NEWBORNS AT A RURAL TERTIARY CARE HOSPITAL.

Recommendation:
Accept as it is .....
Accept after minor revision.....
Accept after major revision -YES
Do not accept (*Reasons below*) .....

Rating	Excel.	Good	Fair	Poor
Originality		_		
Techn. Quality			_	
Clarity			_	
Significance		_		

Reviewer's ID: JPR-094

Detailed Reviewer's Report

 # Reviewer's Report

*****Manuscript Title:** *An Observational Study to Estimate the Prevalence of Congenital Hypothyroidism in Newborns at a Rural Tertiary Care Hospital****

*****Recommendation:** **Major Revision*****

 # Overall Assessment

This manuscript addresses an important neonatal public health problem by estimating the prevalence of congenital hypothyroidism (CH) in a rural tertiary care hospital. The topic is clinically relevant because early diagnosis through newborn screening prevents irreversible intellectual disability. The study is prospective and provides valuable epidemiological information from a rural Indian setting where published data remain limited.

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However, despite its strengths, the manuscript requires **major revision** before it can be considered for publication. The manuscript is excessively long, contains substantial repetition, several methodological inconsistencies, statistical limitations, language issues, and presentation problems.

 # 1. Strengths

1. Clinically Important Topic

**** Congenital hypothyroidism is a major preventable cause of intellectual disability.***
**** Rural prevalence data from India are limited.***
**** The study addresses an important public health gap.***

2. Prospective Study Design

**** Prospective data collection minimizes recall bias.***
**** Ethical approval and informed consent were obtained.***
**** Inclusion and exclusion criteria are clearly defined.***

3. Adequate Sample Size

**** Screening of **919 neonates** provides a reasonable estimate of prevalence.***
**** Sample size calculation has been described.***

4. Standardized Laboratory Method

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**** TSH estimation performed using a standardized immunoenzymometric assay.***

**** Confirmatory testing with Free T4 strengthens diagnostic accuracy.***

5. Public Health Relevance

**** Demonstrates feasibility of newborn screening in rural hospitals.***

**** Supports universal newborn screening policy.***

6. Comprehensive Literature Review

**** References include international guidelines and Indian studies.***

**** Discussion compares findings with previous literature.***

 # 2. Weaknesses

Major Weaknesses

A. Manuscript is excessively lengthy

The manuscript contains extensive repetition.

Examples:

**** Importance of newborn screening repeated multiple times.***

**** Maternal thyroxine explanation repeated repeatedly.***

**** Public health implications repeated in Discussion, Summary and Conclusion.***

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The Discussion alone is almost the length of an entire research article.

Recommendation:

Reduce manuscript length by approximately **35–40%.*

B. Methodological inconsistency

Abstract:

> Study duration = **23 months*

Methods:

> Study duration = **18 months (March 2024–January 2026)*

These statements are inconsistent.

C. Study Design Confusion

The manuscript states:

> Prospective observational cross-sectional study.

A study cannot simultaneously be prospective and purely cross-sectional without clarification.

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Authors should explain:

**** prospective screening cohort?***

**** hospital-based cross-sectional prevalence study?***

D. TSH Cut-off Values

Authors used:

**** <20 normal***

**** 20–40 repeat***

**** > 40 confirmed CH***

Current international recommendations usually recommend:

**** repeat testing***

**** confirmatory serum FT4***

**** age-specific cut-offs***

Authors should justify why these cut-offs were selected.

E. Statistical Power

Only **one confirmed case** was detected.

Therefore:

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**** no meaningful association analysis can be performed.***

Chi-square testing is statistically underpowered.

The manuscript repeatedly reports

> "No statistically significant association"

This conclusion is misleading because the study lacks statistical power.

F. Overinterpretation

Authors conclude

> Universal newborn screening should be implemented

Although clinically reasonable, the study alone cannot justify national implementation because:

**** single centre***
**** one case***
**** limited external validity***

The recommendation should be more cautious.

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G. Single-centre limitation

External validity is limited.

This limitation should receive greater emphasis.

H. Discussion contains unnecessary review material

Almost 60% of Discussion is textbook information.

Discussion should instead focus on:

**** comparison with previous studies***
**** interpretation***
**** strengths***
**** limitations***
**** implications***

 # 3. Minor Weaknesses

English

Several grammatical issues exist.

Examples

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> APGAR

Should be

> Apgar

> At 5 minute

Should be

> At 5 minutes

> Present study was therefore undertaken

Repeated many times.

Several paragraphs begin identically:

> The present study...

This affects readability.

Formatting

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Reference superscripts are inconsistent.

Examples:

```
5–;:
```

```
24,
```

```
39 46
```

Formatting errors should be corrected.

Tables

Table formatting should follow journal style.

Confidence intervals should be consistently expressed.

References

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Some references appear duplicated.

Example

Kaur et al.

appears twice.

WHO guideline repeated.

Reference numbering should be verified.

 # 4. Key Points

Novelty

Moderate.

The study contributes rural Indian prevalence data but does not introduce a new diagnostic method.

Scientific Merit

Good.

Appropriate methodology for prevalence estimation.

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Clinical Importance

High.

Early diagnosis of congenital hypothyroidism has major implications.

Public Health Importance

High.

Supports expansion of newborn screening.

Originality

Moderate.

Many similar prevalence studies already exist.

Quality of Data

Good.

Laboratory protocol appears reliable.

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Literature Review

Very comprehensive but excessively long.

Writing Quality

Moderate.

Requires substantial editing.

 # 5. Scientific Significance

The manuscript provides useful epidemiological evidence regarding congenital hypothyroidism in a rural tertiary hospital.

The prevalence observed

*> **1.09 per 1000 live births***

is consistent with previous Indian studies and contributes additional regional data.

The study demonstrates that:

** congenital hypothyroidism is clinically silent at birth,*

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**** biochemical screening is essential,***

**** rural hospitals can successfully conduct neonatal screening.***

Although only one case was detected, the findings support the feasibility of newborn screening programs in resource-limited settings.

 # 6. Major Comments for Authors

1. Shorten the manuscript considerably.

2. Resolve inconsistency in study duration.

3. Clearly define the study design.

4. Justify TSH cut-off values using current international guidelines.

5. Avoid claiming absence of association when statistical power is inadequate.

6. Reduce textbook content in Discussion.

7. Remove repetitive statements throughout Discussion, Summary and Conclusion.

8. Improve grammar and scientific writing.

9. Verify all references and citation formatting.

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10. Include a STROBE checklist if submitting to journals requiring reporting guidelines.

 # 7. Minor Comments

**** Correct "APGAR" to "Apgar."***
**** Use uniform SI units.***
**** Standardize abbreviations.***
**** Improve table formatting.***
**** Remove duplicated references.***
**** Ensure all percentages match raw numbers.***
**** Add flow diagram of participant selection.***
**** Mention funding and conflict of interest explicitly.***

 # 8. Overall Recommendation

**Major Revision**

Justification

The study addresses an important clinical problem and provides useful prevalence data from a rural tertiary care centre. The methodology is generally appropriate, ethical considerations are addressed, and laboratory confirmation strengthens the diagnosis.

However, the manuscript requires substantial revision due to:

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**** excessive repetition,***

**** methodological inconsistencies,***

**** statistical limitations,***

**** overinterpretation of findings,***

**** language and formatting issues,***

**** unnecessarily lengthy discussion.***

These issues affect readability and scientific rigor but are **correctable**. Following major revision, the manuscript could make a worthwhile contribution to the literature on neonatal screening for congenital hypothyroidism in rural India.

This manuscript **requires Major Revision**, not because the topic lacks importance, but because there are **important scientific, methodological, statistical, reporting, and editorial weaknesses** that prevent acceptance in its current form. Below is a **line-by-line justification** suitable for a reviewer report.

Overall Recommendation: MAJOR REVISION

Overall Justification

The study addresses an important public health issue and includes a relatively large newborn cohort (n=919). However, substantial revisions are required to improve scientific rigor, methodology, statistical analysis, interpretation of results, reporting consistency, and manuscript structure. Several conclusions are stronger than the data support, particularly because only one confirmed case of congenital hypothyroidism was identified.

LINE-BY-LINE MAJOR REVISION COMMENTS

Line No.	Issue	Why Major Revision Required
7-13	Background too general	Needs updated global and Indian epidemiological statistics with recent guidelines (ESPE/ATA/ICMR).

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Line No.	Issue	Why Major Revision Required
15-16	Objectives vague	Need clearly define primary and secondary outcome variables.
18	Study described as "prospective observational cross-sectional"	Cross-sectional studies are not usually termed prospective. Clarify actual study design.
19	Study duration says 23 months	Later Methods mentions 18 months (March 2024-Jan 2026). Major inconsistency.
21	Exclusion of mothers with hypothyroidism	This exclusion limits prevalence estimation and introduces selection bias. Justify scientifically.
22	Serum TSH only	Most newborn screening uses dried blood spot TSH. Explain why venous serum TSH was selected.
23	Repeat testing criteria	Need complete confirmatory diagnostic protocol.
26-30	Only one CH case	Association analyses become statistically underpowered. Results should be interpreted cautiously.
31-35	Conclusion overstates findings	Universal screening recommendation is reasonable but stronger evidence is needed before broad policy conclusions.

INTRODUCTION

Line	Issue	Reason
43-57	Introduction excessively long	Can be shortened by 30–40% without losing content.
64-70	Embryology section too detailed	Not directly relevant to prevalence study.
66	Formatting error ("[8]–;:")	Reference formatting corrupted.
70	Citation formatting incorrect	Needs correction throughout manuscript.
71-76	Physiology repeated later	Avoid repetition.
84-90	Screening discussion repeated multiple times	Redundancy.
92-99	Gap statement weak	Need clearly identify what knowledge gap this study fills.
100-103	Study rationale	Should explain why this hospital population was selected.

AIMS & OBJECTIVES

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Line	Issue	Reason
118-123	Objectives not measurable	Need specify outcome variables and statistical comparisons.

MATERIALS AND METHODS

Study Design

Line	Issue	Reason
138-145	Study design inconsistent	Prospective vs cross-sectional requires clarification.
145	Duration incorrect	March 2024-Jan 2026 equals approximately 23 months, not 18 months.

Study Population

Line	Issue	Reason
147-151	Sampling method absent	Need mention consecutive sampling or convenience sampling.
149-151	TSH screening window	Need cite guideline supporting 72 h–7 days.

Inclusion/Exclusion

Line	Issue	Reason
164-165	Excluding maternal hypothyroidism	Produces selection bias and underestimates prevalence.
166-169	Major anomalies excluded	Need explain rationale.

Maternal Variables

Line	Issue	Reason
184	Iodine assessed only by history	Self-reported iodized salt use is unreliable. State limitation.

Anthropometry

Line	Issue	Reason
205	Gestational age	Need specify Ballard score when first-trimester scan

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Line	Issue	Reason
determination	unavailable.	

Laboratory Methods

Line	Issue	Reason
227-230	Assay lacks analytical details	Need sensitivity, specificity, CV%, calibration, reference ranges.
229	Internal QC mentioned	External quality assurance not described.

Diagnostic Criteria

Line	Issue	Reason
233-241	TSH cutoffs need references	Explain why 20 and 40 µIU/mL were selected.
239	Free T4 measured only in abnormal cases	State assay method.

Sample Size

Line	Issue	Reason
245-263	Formula correct but assumptions poorly justified	Need explain precision selection (0.296%).
254	Reference study cited	Need justify applicability to current rural population.

Statistical Analysis

Line	Issue	Reason
280-285	Chi-square inappropriate	Only one event. Fisher exact only.
283	t-test impossible	Cannot compare groups with one CH case.
285	Need specify normality testing	Missing.

RESULTS

Maternal Characteristics

Line	Issue	Reason
292-300	No confidence intervals	Only descriptive percentages.

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Line	Issue	Reason
297-300	100% iodized salt use	Possible reporting bias.

Neonatal Characteristics

Line	Issue	Reason
314-315	100% APGAR 9 at 5 min	Highly unusual. Needs verification.

Table 3

Line	Issue	Reason
321	Mean>Median	Distribution skewed; median more appropriate.
323	Repeat category inconsistent	Earlier threshold differs.
324	Prevalence calculation correct	Confidence interval reported inconsistently.

Table 4

Line	Issue	Reason
330-337	No statistical test shown	Since only one event, statistical testing inappropriate.

DISCUSSION

Line	Issue	Reason
345-353	Discussion repeats Results	Should interpret rather than restate.
355-369	Comparisons acceptable	Need more recent Indian literature (2022–2025).
370-379	Clinical findings repeated	Redundant.
380-396	Methodology repeated	Belongs in Methods.
397 onwards	Discussion excessively long	Can reduce by nearly 40%.
452-459	States no association	Cannot conclude because study underpowered.
467 onwards	Large repetition	Public health implications repeated several times.
529-591	Entire confirmed case discussion	Should be separate case description or removed.

SUMMARY

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Line	Issue	Reason
595-666	Too detailed	Summary should be concise.

CONCLUSION

Line	Issue	Reason
671-695	Repeated conclusions	Merge into one concise conclusion.
681-695	Policy recommendations too strong	Single-center study with one case insufficient for national recommendations.

LIMITATIONS

Line	Issue	Reason
703-723	Need additional limitations	Mention selection bias, serum TSH-only screening, single-center design, absence of imaging in all neonates.

REFERENCES

Line	Issue	Reason
Throughout	Duplicate references	Reference 36 duplicates Reference 26; Reference 46 duplicates Reference 31.
Throughout	Formatting inconsistent	Journal abbreviations, DOI formatting, punctuation inconsistent.
Throughout	Some references outdated	Need include latest ESPE, ATA, ICMR guidelines (2023–2025).

Additional Scientific Concerns

1. Statistical Power

Only one confirmed CH case was detected. Therefore:

Association analyses are statistically invalid.

Risk factor analysis cannot be interpreted.

Chi-square testing is inappropriate.

Fisher's exact test should be used where applicable.

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2. Overinterpretation

The manuscript repeatedly states:

universal screening should be implemented

findings strengthen national policy

public health implications

These conclusions exceed the evidence generated from a single-center prevalence study with one confirmed case.

3. Missing Information

The manuscript should include:

STROBE checklist compliance.

Participant flow diagram.

Missing data handling.

Laboratory quality assurance.

Follow-up duration of confirmed case.

Levothyroxine treatment details.

Imaging confirmation methodology.

Ethical approval number.

4. Language Issues

Numerous problems remain:

repetitive sentences

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inconsistent tense

duplicated paragraphs

formatting errors

citation corruption ("⁸–;:", ";:›")

inconsistent units (µIU/mL)

spacing issues

Final Recommendation

Decision: Major Revision

Reasons

Methodological inconsistencies (study duration and study design)

Underpowered statistical analysis

Overstated conclusions

Excessive repetition in Introduction and Discussion

Inadequate reporting of laboratory methods

Missing STROBE-compliant reporting

Inconsistent statistical methodology

Reference duplication and formatting errors

Editorial and language revisions required throughout

Overall assessment: The study addresses an important topic and provides useful rural prevalence data. However, substantial revisions are necessary before the manuscript can be considered for publication. The authors should improve methodological transparency,

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revise the statistical analysis, reduce redundancy, temper conclusions, correct inconsistencies, and update the literature to meet the standards expected of a peer-reviewed journal.