Title: Standardized Voice and Genetic Data Analysis for Early Detection of Laryngeal Cancer Based on ISO Guidelines

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Title:
Standardized Voice and Genetic Data Analysis for Early Detection of Laryngeal Cancer Based on ISO Guidelines

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Abstract:
This study introduces a scientifically grounded, ISO-compliant framework for early and non-invasive detection of laryngeal cancer. By integrating acoustic voice analysis with genetic biomarker evaluation and adhering to international ISO standards, we propose a multi-modal diagnostic model with strong clinical potential. Voice samples were collected under standardized conditions, and genetic data were extracted from saliva. Machine learning algorithms, validated according to ISO/IEC quality protocols, were employed to analyze the combined dataset, achieving high diagnostic accuracy.

1. Introduction:
Laryngeal cancer adversely affects speech, respiration, and overall quality of life. Traditional diagnostic procedures are often invasive, resource-intensive, and unsuitable for routine screening. With advancements in signal processing and genomics, it is now feasible to detect early signs of malignancy through non-invasive methods. This study aims to establish a standardized pipeline for integrating

acoustic and genetic data in early detection, ensuring compliance with relevant ISO standards for medical, laboratory, and software quality.

2. Background:
Prior research has demonstrated a correlation between vocal irregularities and laryngeal disorders (Zhang et al., 2021; Lee et al., 2019). Additionally, specific genetic mutations, such as those in TP53, NOTCH1, and EGFR, have been linked to increased cancer susceptibility (Kim et al., 2022). Despite these findings, few studies have successfully merged acoustic and genomic data within a standardized diagnostic infrastructure. Our study addresses this gap by implementing a unified system guided by ISO standards.

3. Materials and Methods:
Participants: Fifty volunteers (25 diagnosed with early-stage laryngeal cancer and 25 healthy controls).

Data Collection:
- Acoustic Data: Voice samples (sustained vowels and reading tasks) recorded using ISO 61672-calibrated microphones in an ISO 3745-compliant anechoic chamber.
- Genetic Data: Saliva samples analyzed for TP53, NOTCH1, and EGFR markers under ISO 15189-certified protocols.

Acoustic Features Extracted:
- Jitter
- Shimmer
- Harmonics-to-Noise Ratio (HNR)
- Cepstral Peak Prominence (CPP)

Software and Processing:
- MATLAB and Python, validated under ISO/IEC 25051.
- Data protection and consent protocols followed ISO/IEC 27001 guidelines.

4. AI Modeling and Evaluation:

The dataset was processed using supervised learning algorithms, including Support Vector Machines (SVM) and neural networks. Cross-validation methods ensured robustness. Performance metrics —accuracy, sensitivity, and specificity—were calculated, and ROC curves were used for model evaluation. The integrated model achieved an accuracy of 88%, sensitivity of 86%, and specificity of 90%.

5. Results:
- Statistically significant differences were observed in jitter and HNR between cancer patients and healthy individuals ($p < 0.01$).
- Integration of genetic markers improved classifier precision by 7%.
- The diagnostic model performed consistently across voice types.

Table 1: Performance Summary

Model Type	Accuracy	Sensitivity	Specificity
Acoustic + Genetic	88%	86%	90%
Acoustic Only	81%	78%	83%
Genetic Only	76%	72%	79%

6. Discussion:
The combination of acoustic and genetic analysis presents a novel, comprehensive approach to early cancer detection. The system's high diagnostic accuracy, supported by ISO-standard methodologies, highlights its feasibility for future clinical deployment. Key limitations include the relatively small sample size and lack of multilingual voice data. Future studies should aim for more diverse datasets and longitudinal evaluations.

7. Ethical Considerations:
All procedures adhered to ISO/IEC 27001 and ISO 14155 guidelines. Participants provided informed consent. Data were anonymized, encrypted, and used solely for research purposes.

8. Conclusion:

This research validates an ISO-compliant, scalable system for early, non-invasive detection of laryngeal cancer. By uniting signal processing and genomic screening within a rigorous quality framework, the model offers a viable pathway for integrating such diagnostics into telehealth and clinical settings.

9. References:

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