Official Title: Three-Dimensional Computed Tomography Assessment of Arcuate Foramen Variants and Their Surgical Implications: A Retrospective Observational Study

NCT Number: [To be assigned after registration]

Document Date: August 11, 2025

1. Background and Rationale
The arcuate foramen (AF) is an anatomical variation of the atlas (C1 vertebra) resulting from ossification of the posterior atlanto-occipital membrane, forming a bony bridge over the vertebral artery groove. While frequently asymptomatic, AF has been associated with vertebrobasilar insufficiency, cervicogenic headache, and neck pain. Importantly, AF may increase the risk of vertebral artery or suboccipital nerve injury during craniovertebral junction surgery. This study aims to determine the prevalence and types of AF in a Turkish population using high-resolution three-dimensional computed tomography (3D CT) and to evaluate its potential surgical implications.

2. Objectives
Primary Objective: To determine the prevalence of complete and incomplete AF variants using 3D CT.
Secondary Objectives: (1) To assess the association between AF presence and demographic variables; (2) To evaluate interobserver agreement in AF detection.

3. Study Design
This is a retrospective, cross-sectional observational study conducted at Giresun University Faculty of Medicine. The study population includes adult patients who underwent head CT or CTA between January 2023 and July 2025.

4. Methods
Inclusion Criteria: Age $\geq$ 18 years; high-quality CT or CTA images including atlas vertebra; complete demographic data. Exclusion Criteria: Significant motion or metallic artifact; prior cervical surgery or trauma; congenital anomalies obscuring anatomy. Imaging Technique: All scans were acquired using FUJIFILM SUPRIA CT system and reconstructed using OsiriX MD software with a 3D volume rendering technique. AF Classification: Complete (full bony ring) or incomplete (partial bony projection), further categorized by side (right, left, bilateral).

5. Outcome Measures
Primary Outcome: Prevalence of complete and incomplete AF with 95% confidence intervals. Secondary Outcomes: Association between AF and age/sex; interobserver agreement measured by Cohen's Kappa.

6. Statistical Analysis Plan
Descriptive statistics will summarize continuous variables as mean ± standard deviation and categorical variables as frequencies and percentages. Chi-square or Fisher's exact test will be used for categorical comparisons, and independent t-test for continuous variables. Interobserver agreement will be calculated using Cohen's Kappa. A p-value < 0.05 will be considered statistically significant. Post-hoc power analysis indicated a study power of 83% with 200 participants for an expected prevalence of 15% ($\alpha = 0.05$).

7. Ethics and Regulatory Compliance
The study protocol was approved by the Giresun University Faculty of Medicine Ethics Committee (Approval No: E-53593568-771-250207806, Date: July 31, 2024). All data were de-identified prior to analysis in compliance with relevant data protection regulations.

8. References
1. Elliott RE, Tanweer O. World Neurosurg. 2014;82:e335–43. 2. P■kala PA, Henry BM, et al. J Neurosurg Spine. 2017;27(3):276-290. 3. Arslan D, Özer MA, Govsa F, Kiti■ Ö. World Neurosurg. 2018;113:e579–e585. 4. Cicek ED, Keser N, Is M, Ates O. Turk Neurosurg. 2022;32(4):571-577. 5. Keser N, Ç■kla U, Özayd■n B, et al. Istanbul Med J. 2019;20(5):377-381.

Study Protocol and Statistical Analysis Plan - Summary

Study Protocol

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Objectives: Primary Objective: To determine the prevalence of complete and incomplete AF variants using 3D CT. Secondary Objectives: (1) To assess the association between AF presence and demographic factors; (2) To evaluate interobserver agreement in AF detection.

Study Design: Retrospective, cross-sectional observational study conducted at Giresun University Faculty of Medicine. Data were collected from January 2023 to July 2025.

Methods: Inclusion criteria: Age $\geq$ 18 years; high-quality CT or CTA images including the atlas; complete demographic data. Exclusion criteria: Motion or metallic artifact; prior cervical surgery or trauma; congenital anomalies obscuring anatomy. Imaging was performed on a FUJIFILM SUPRIA CT system and reconstructed using OsiriX MD with 3D volume rendering. AF was classified as complete (full bony ring) or incomplete (partial bony projection) and categorized by side (right, left, bilateral).

Outcome Measures: Primary: Prevalence of complete and incomplete AF (95% CI). Secondary: Association with age/sex; interobserver agreement (Cohen's Kappa).

Statistical Analysis Plan

Descriptive statistics: Continuous variables as mean ± standard deviation; categorical variables as frequencies and percentages. Chi-square or Fisher's exact test for categorical data; independent t-test for continuous data. Interobserver agreement assessed by Cohen's Kappa. Significance level set at $p < 0.05$. Post-hoc power analysis indicated 83% power with 200 participants for an expected prevalence of 15% (α = 0.05).