Journal of Clinical and Medical Images

Research Article

ISSN: 2640-9615 | Volume 8

Radiation Exposure in Pediatric Cochlear Implant Recipients: Estimation and Significance

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Received: 03 Jan 2025
Accepted: 23 Jan 2025
Published: 29 Jan 2025
J Short Name: JCMI

Keywords:

Cochlear Implant;Computed Tomography; Radiation Exposure;Radiation Dose

Citation:

Nezar Hamed, Radiation Exposure in Pediatric Cochlear Implant Recipients: Estimation and Significance. J Clin Med Img. 2025; V8(7): 1-8

1. Abstract

1.1. Objectives

Computed tomography (CT) is valuable for cochlear implant (CI) assessment, but it exposes patients to ionizing radiation, which is especially concerning for children. This study aims to evaluate the likelihood of pediatric CI patients undergoing multiple CT scans within a short period and estimate the Temporal bone CT (TBCT) radiation dose.

1.2. Methods

This cross-sectional study estimates radiation exposure in pediatric CI recipients who underwent surgery at a tertiary care hospital in Saudi Arabia between July 2002 and November 2022. We analyzed preoperative and postoperative TBCT scans to assess the likelihood of repeated CT scan exposure, including the number of scans, the interval between them, age at the time of the scan, gender, and the number of scans per year. Additionally, we estimated radiation exposure for each patient based on the scanner radiation dose report of each examination.

1.3. Results

A total of 737 pediatric CI patients were included in this cohort. Among them, 12.6% received additional postoperative TBCT scans. None of them developed radiation-induced medical conditions during the follow-up post-implantation. Dose Length Product (DLP) and Predicted Effective Dose showed negligible correlations with patient age, while CT Dose Index (CTDI) exhibited a significantly weak positive correlation. Comparative analysis indicated that DLP, CTDI, and Predicted Effective Dose were higher post-operatively.

1.4. Conclusion

This study underscores the susceptibility of pediatric CI recipients to receiving multiple TBCT scans within a short period for various reasons, which may increase their radiation exposure. Clinicians

should critically evaluate the necessity of each CT scan and consider lower-radiation alternatives.

2. Introduction

Cochlear implant (CI) surgery has become an essential treatment option for children with severe to profound hearing loss [1,2]. Temporal bone computed tomography (TBCT) is a crucial preoperative assessment for CI surgery and is the preferred imaging modality for evaluating osseous abnormalities. TBCT with magnetic resonance imaging (MRI) offer complementary information and are frequently used together in the preoperative evaluation of pediatric candidates for cochlear implantation [3]. In addition, Computed tomography (CT) is a valuable modality for the postoperative evaluation of electrode depth and placement [4]. However, CT scans expose CI patients to ionizing radiation, which is particularly concerning for children.Exposure to ionizing radiation from computed tomography (CT) can cause DNA damage, leading to mutations that may result in cancer or other adverse health effects [5]. Recent studies found that there are specific types of cancer that are associated with radiation exposure in children including leukemia, brain tumors, and solid tumors such as thyroid and breast cancer. The risk of cancer development is highest in children who receive high doses of radiation at a young age, because of their growing body and long-life expectancy [6]. Moreover, children are more susceptible to radiation-induced cancer and genetic mutations due to their rapidly dividing cells and immature immune systems [7,8].

The amount of radiation exposure from a TBCT scan can vary depending on the specific protocol used by the imaging facility, as well as the body size and age of the child [9]. A previous study reported that the mean effective doses of the TBCT for patients aged 5 and 10 were 0.85 mSv and 0.75 mSv, respectively [10]. According to a study published in the American Journal of Neuroradiology, the effective radiation dose of the TBCT scan in children ranges from approximately 0.5 to 2.5 millisieverts (mSv) [11]. However, TBCT scans typically result in a relatively low level of radiation exposure. Adherence to optimization principles, epitomized by the acronym As Low As Reasonably Achievable (ALARA) [12], is crucial in minimizing the risk for CI patients exposed to radiation, thus ensuring compliance with both international and national regulations. This principle underscores the importance of maintaining radiation exposure at the lowest feasible levels, while considering economic and social factors.TBCT is requested preoperatively in most CI centers for evaluation, while in some centers, it is also requested postoperatively, either as a routine assessment or due to complications. However, the potential risks associated with ionizing radiation exposure in children should be carefully weighed against the benefits of TBCT. We are concerned about the leniency of healthcare professionals and the CI center in requesting multiple CT scans for CI patient evaluations. Despite the low radiation dose of TBCT scans, the cumulative exposure from multiple scans could increase the risk of stochastic effects in the future, especially for pediatric patients. This study aims to assess the likelihood of exposure to multiple CT scans within a short period and estimate the TBCT radiation dose in pediatric CI patients. In addition, these values could be pivotal in determining the National Diagnostic Reference Levels (NDRLs) specifically for TBCT in the pediatric age group. These findings could lead to amendments in the protocols of many CI centers, promoting the use of alternative imaging modalities to reduce radiation exposure before CI surgery.

3. Methodology

3.1.Study Design

This cross-sectional study was conducted at King Abdullah Specialist Ear Center, Riyadh, Saudi Arabia to explore radiation exposure in pediatric CI recipients. The study has received ethical approval from the Institutional Review Board at King Saud University (Ref. No. 23/0295/IRB). In addition, the patient's confidentiality is secured, and the hospital policy as well as the regulations are followed.

3.2.Patients' Selection

All pediatric patients (age ≤ 18 years), who underwent CI surgery in a tertiary care hospital in Saudi Arabia between July 2002 and November 2022 have been included in this study, including both genders. All patients were on regular follow-up for more than one year after cochlear implantation, with the inclusion criteria of having at least one pre-operative high-resolution TBCT as routine preoperative assessment. The exclusion criteria included all patients with missing data.

3.3.Data Collection and Management

All TBCT scans in our database were included in our study to estimate the probability of multiple CT scan exposures in pediatric CI patients. We analyzed both preoperative and postoperative TBCT scans to evaluate the likelihood of repeated CT scan exposure. This analysis included the number of TBCT scans and the interval between them. In addition to the age at the time of the CT scan, gender, and number of CT scans per year. Furthermore, we estimated the radiation exposure for each patient based on the reported radiation dose (DLP and CTDI) from each examination. These radiation dose metrics have been available only for TBCT scans performed since 2017 using the same CT device, following the implementation of standardized procedures for all patients at our institute. Subsequently, we calculated the predicted effective dose. Furthermore, the radiological doses were analyzed to determine the radiation exposure from TBCT in pediatric CI patients. Data collection and management were performed using Microsoft Excel (version 16.3; Microsoft, Seattle, WA, USA).

3.4.TBCT Protocol

In this study, the GE Revolution CT scanner series, specifically model serial SA1209VT01, was employed for its advanced imaging capabilities. The protocol for TBCT scans was meticulously designed to ensure high-resolution imaging while minimizing radiation exposure, with particular consideration for the heightened sensitivity of pediatric patients to radiation. The specific parameters for TBCT scans were as follows: slice thickness of 0.625 mm, tube current of 230 mA, tube voltage of 140 kV, and rotation time of 1 second, with reconstruction at 0.3 mm in axial and coronal views. The scanner performed scouts at 80 kV and 10 mA to determine the appropriate scan parameters for the implant site, ensuring accurate imaging of the inner ear structures with minimal radiation dose. Advanced features of the GE Revolution CT scanner include ASiR-V, GE's next-generation iterative reconstruction technology, which significantly reduces noise levels, improves low-contrast detectability, and decreases the radiation dose by up to 82%, particularly benefiting pediatric patients.The detailed protocols for CI scanning included a tube current of 80 mA fixed with Organ Dose Modulation (ODM) to protect radiosensitive organs, a tube voltage of 100 kV, and the use of a small bowtie filter for additional filtration. The scan range was from S38.579 to I1.108 mm, with a scan length of 39.7 mm and a scanned field of view (SFOV) of 32 cm. The acquisition mode was sequential, with a noise index of 21, pixel spacing of 0.342/0.342 mm/px, slice thickness of 0.625 mm, and a bone+2 filter kernel. Each rotation included 2,496 views, with an iterative reconstruction level set at 30%. The volumetric computed tomography dose index (CTDIvol) was 7.9 mGy. These protocols were meticulously designed to provide the high-resolution images necessary for the surgical planning of CI device insertions while ensuring patient safety through minimized radiation exposure. The use of organ dose modulation was particularly crucial for protecting radiosensitive organs such as the eye lenses.

3.5.Statistical Analysis

All data were fed for statistical analysis using R Software for Statistical Computing version 4.2.2 (Vienna, Austria). Descriptive analysis was carried out for all patients' baseline demographics using mean, standard deviation, and range for quantitative data and count and percentage for qualitative ones. The prevalence of patients performing more than one TBCT within less than one-year interval was detected among 47 CI patients. Average CTDI, DLP, and Estimated Effective Dose (mSv) for Preoperative TBCT scan with corresponding standard deviations were calculated among 110 CT-exposed patients. Normality assumptions were checked using the Shapiro–Wilk test. Note: The comparative analyses in Table 3 were conducted using the Wilcoxon signed-rank test for paired samples because all reported measures violated the normality assumptions tested by the Shapiro–Wilk test.

4. Results

A total of 737 pediatric patients underwent cochlear implantation between 2012 and 2022, with each patient undergoing preoperative TBCT scans as part of routine pre-CI assessment. Among this cohort, 93 patients (12.6%) received additional postoperative TBCT scans. Upon considering the duration between CT scans, particularly those conducted within a period of less than one year, incorporating both preoperative and postoperative scans, it was observed that 47 out of the 737 patients (6.4%) underwent at least one postoperative CT scan in addition to the preoperative scans within less than one year. Among this subgroup, 43 patients underwent two postoperative CT scans, while three patients underwent three scans within this defined timeframe. Notably, among the 737 individuals studied, only one patient (0.1%) received two CT scans within one year on two separate occasions, with the first instance occurring in 2017 and the second between 2020 and 2021 (Table 1). None of the patients developed cancer or any new medical conditions related to radiation exposure during the follow-up period post-implantation.The dose reports, which include the CTDI and DLP, for the preoperative TBCT were only available for 110 children (Table 2). The average age at the time of the CT scan was 5.6 ± 4.2 years. Among these patients, 54.5% were male and 45.5% were female.

4.1. Pre-Operative Radiation Parameters Stratified by Age Group

For patients aged 0 to 5 years, the average DLP was 352.8 ± 87.6 mGy·cm, with a median of 335.5 mGy·cm and interquartile range from 334.7 mGy·cm to 335.9 mGy·cm (represented 25% to 75% percentile). The average CTDI was 34.5 ± 7.9 mGy, with a median of 33.5 mGy and interquartile range from 33.5 mGy to 34.1 mGy. The average Predicted Effective Dose was 0.7 ± 0.2 mSv, with a median of 0.7 mSv and an interquartile range from 0.7 mSv to 0.7 mSv (Table 2).For patients aged 6 to 18 years, the average DLP was 360.5 ± 95.0 mGy·cm, with a median of 335.4 mGy·cm and an interquartile range from 335.1 mGy·cm to 335.9 mGy·cm. The average CTDI was 37.0 ± 7.0 mGy, with a median of 33.5 mGy and interquartile range from 33.5 mGy to 34.7 mGy. The average Predicted Effective Dose was 0.8 ± 0.2 mSv, with a median of 0.7 mSv and an interquartile range from 0.7 mSv to 0.7 mSv (Table 2).

4.2. Correlation Between Age and Radiation Parameters

Figure 1 illustrates the Spearman correlation coefficients between patient age at the time of the TBCT scan and the radiation parameters. Both DLP and Predicted Effective Dose showed negligible and non-significant correlations with patient age ($r = 0.052$, $r = 0.056$, respectively) (Figure 1-A, 1-C). However, CTDI exhibited a significant weak positive correlation with age ($r = 0.2$, $p = 0.036$) (Figure 1-B).

4.3. Gender and Pre-operative Radiation Parameters

Our analysis examined the relationship between patients' gender and radiation parameters. The findings indicated the average DLP, average CTDI, and average predicted pre-operative effective dose, with error bars representing standard deviations (Figure 2).

Table 1: Cochlear implanted patients exposed to more than one CT-Temporal Bone in less than one year.

Patients' characteristics	Levels	Overall (N = 47)
Gender	Female	23 (48.9%)
	Male	24 (51.1%)
Laterality	Bilateral Sequential	11 (23.4%)
	Bilateral Simultaneous	19 (40.4%)
	Unilateral	17 (36.2%)
Age at implantation (years)	Mean (SD)	3.5 ± 1.8
	Min – Max	1.4 - 9.0
Age at pre-op CT (years)	Mean (SD)	2.4 ± 1.4
	Min – Max	0.83 - 7.7
Age at post-op CT (years)	Mean (SD)	4.3 ± 2.2
	Min – Max	1.4 - 10.1
No. of CT per year	2 CTs	44 (93.6%)
	2+2 CTs	1 (2.1%)
	3 CTs	2 (4.3%)

Data are represented as mean ± standard deviation, range, and count (percentage).

Table 2: Baseline demographics, Average Dose-Length Product (DLP), Computed Tomography Dose Index (CTDI) and Estimated Effective Dose for Preoperative Temporal Bone CT scan exposed patients.

Demographics	levels	Overall (N = 110)	
Age at CT scan Pre-CI (Years)	Mean (SD)	5.6 ± 4.2	
	Min – Max	0.9 - 18.0	
Gender	Female	50 (45.5%)	
	Male	60 (54.5%)	
CT radiation parameters by age group			
DLP (mGy.cm)	0 - 5 years	Mean (SD)	352.8 ± 87.6
		Min – Max	104.70 - 725.10
		Median (25% - 75%)	335.5 (334.7 to 335.9)
	6 – 18 years	Mean (SD)	360.5 ± 95.0
		Min – Max	276.60 - 861.20
		Median (25% - 75%)	335.4 (335.1 to 335.9)
CTDI (mGy)	0 - 5 years	Mean (SD)	34.5 ± 7.9
		Min – Max	0.20 - 67.40
		Median (25% - 75%)	33.5 (33.5 to 34.1)
	6 – 18 years	Mean (SD)	37.0 ± 7.0
		Min – Max	33.40 - 67.40
		Median (25% - 75%)	33.5 (33.5 to 34.7)
Predicted Effective Dose Pre-op. (mSv)	0 - 5 years	Mean (SD)	0.7 ± 0.2
		Min – Max	0.22 - 1.52
		Median (25% - 75%)	0.7 (0.7 to 0.7)
	6 – 18 years	Mean (SD)	0.8 ± 0.2
		Min – Max	0.58 - 1.81
		Median (25% - 75%)	0.7 (0.7 to 0.7)

Data are represented as mean ± standard deviation, range, median (25% percentile – 75% percentile), and count (percentage).

Table 3: Comparative analysis between pre-operative and post-operative CT radiation parameters.

CT radiation parameters	Pre-operative Mean (SD)	Post-operative Mean (SD)	P value*
DLP (mGy.cm)	356.1 (90.6)	483.4 (240.2)	0.402
CTDI (mGy)	35.6 (7.6)	45.3 (15.9)	0.402
Predicted Effective Dose Pre-op. (mSv)	0.75 (0.19)	1.02 (0.50)	0.469

* Wilcoxon signed-rank test for paired samples. Dose-Length Product (DLP), Computed Tomography Dose Index (CTDI)

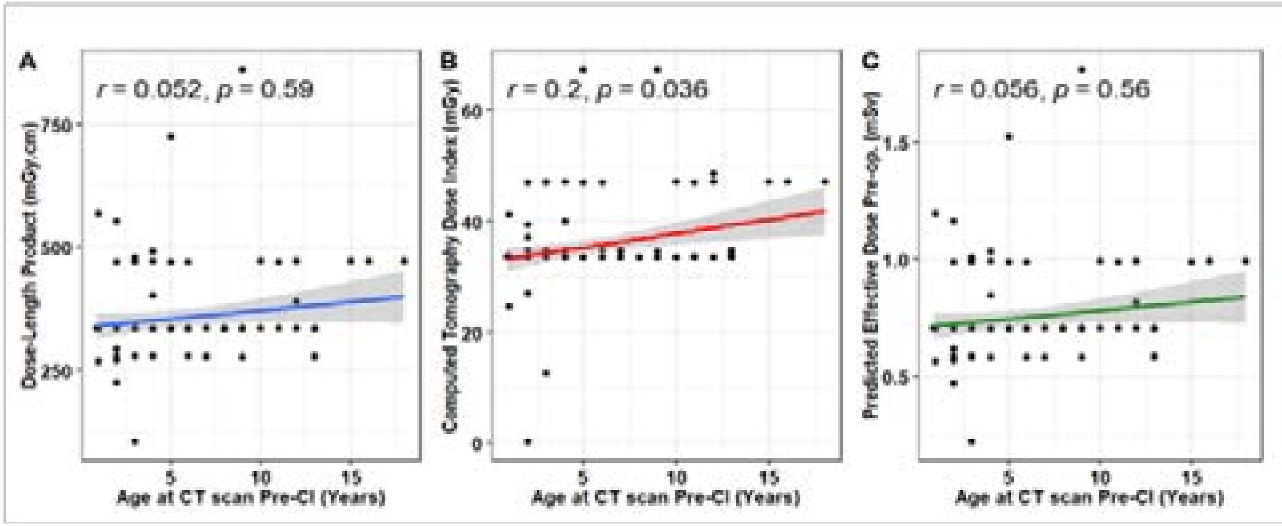

Figure 1: Relationship between Age at CT scan pre-operative and radiation parameters; A: for Dose-Length Product (DLP); B: for Computed Tomography Dose Index (CTDI); and C: for Predicted Effective Dose Pre-operative (mSv); Spearman correlation coefficients showed a significant weak positive correlation of age of patients at CT scan pre-cochlear implantation with only CTDI.

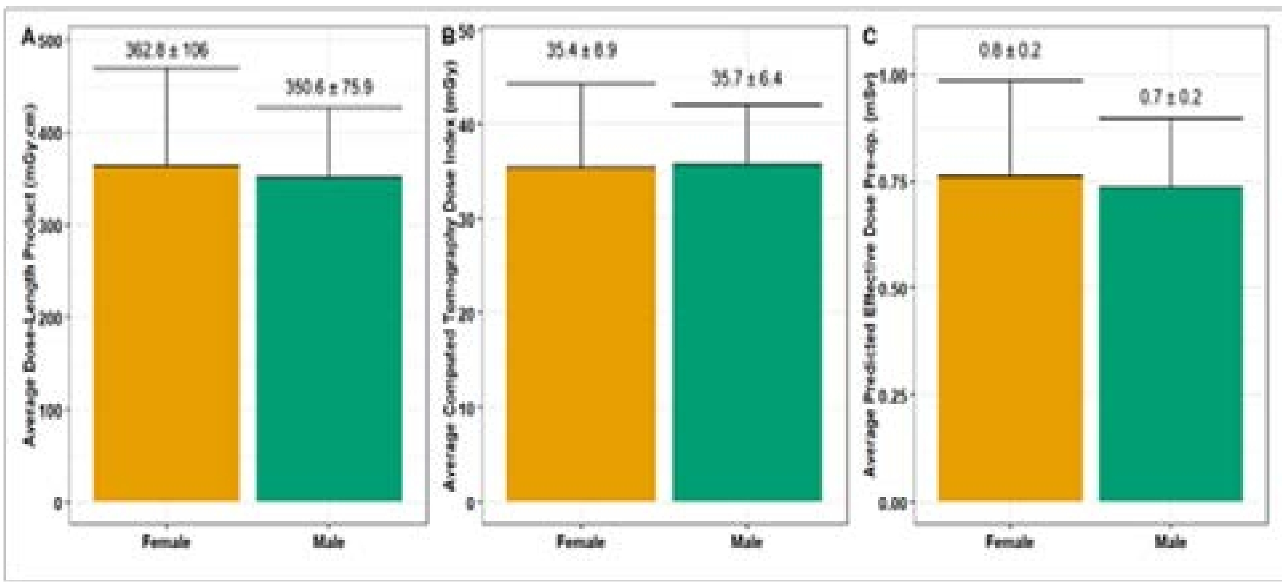

Figure 2: Relationship between patients' gender and radiation parameters; A: for Average Dose-Length Product (DLP); B: for Average Computed Tomography Dose Index (CTDI); and C: for Average Predicted Effective Dose Pre-operative (mSv); with error bars representing the standard deviations.

4.3. Comparative Analysis of Pre- and Post-Operative Radiation Parameters

A subset of seven pediatric CI patients had documented radiation parameters for both pre- and post-operative TBCT scans. Comparative analysis of DLP, CTDI, and Predicted Effective Dose between pre- and post-operative measurements indicated an increase in all parameters post-operatively. However, these increases were not statistically significant ($p > 0.05$), likely due to the small sample size (Table 3).

5. Discussion

This study indicates that these patients are susceptible to undergoing multiple TBCT scans in a short period for various reasons. However, postoperative TBCT scans are not routinely requested at our center. Nevertheless, some institutions consider imaging after CI essential for identifying the electrode array position [4,13]. However, X-ray imaging has proven to be an effective, and reliable method for verifying CI electrode array insertion [14,15]. This highlights the necessity for minimizing exposure in repetitive imaging. In addition, this indicates a degree of variability in the use of postoperative imaging, which could be influenced by clinical needs or varying practices across different periods or clinicians. Regarding the local protocol of the Saudi Food and Drug Administration (SFDA), the National Diagnostic Reference Levels (NDRLs) establish CT dose limits for various body parts in adults and children, including head CT scans. However, specific dose limitations for TBCT have not yet been determined. As TBCT is considered part of head imaging, its radiation dose should ideally be comparable to or lower than that of head CT scans, despite TBCT typically having thinner slice thicknesses than head CT scans. In the SFDA's NDRLs, pediatric populations are divided into two age groups (0-5 years and 6-15 years). For head CT scans, the established NDRLs in Saudi Arabia are DLP = 482 mGy.cm and CTDI = 28 mGy for ages 0-5 years, and DLP = 697 mGy.cm and CTDI = 42 mGy for ages 6-15 years [16]. Overall, our study found that the radiation dose from TBCT did not exceed the head CT dose limits established by the SFDA for each age group, except for the CTDI in the 0-5 years age group.The effective dose is a measure of the radiation dose to the entire body and takes into account the type of radiation and the sensitivity of different organs and tissues to radiation. In comparison to our local TBCT imaging protocol, the effective dose for TBCT reported in the literature varied widely ranging from 0.25 mSv for the low-dose protocol [11] to as high as 2.6 mSv [17]. This signifies the importance of imaging protocols in optimizing radiation exposure. Fortunately, our results were consistent with previous studies regarding the TBCT radiation parameters for the same age group. However, the use of low-dose TBCT protocol has been demonstrated to be effective in assessing the anatomy of the inner and middle ear in children, the protocol did not take into consideration the presence of artifacts such as cochlear implants [11]. Furthermore, although it resulted in a lower effective dose, the quality of the images was slightly altered, requiring more cautiousness when evaluating and interpreting low-dose CT images. The Low-dose protocol provides sufficient images with much lower radiation exposure.

The stratification of radiation parameters by age group revealed that younger children (0-5 years) and older children (6-18 years) exhibited similar dose metrics. The average DLP and CTDI values were slightly higher in the older age group. Furthermore, the weak but significant positive correlation between patient age and CTDI suggests that older children might be exposed to slightly higher doses, potentially due to differences in head size and the corresponding adjustments in scanning parameters. However, no significant correlations were found between age and either DLP or predicted effective dose, suggesting that factors other than age may influence these metrics. The gender analysis revealed no significant differences in radiation exposure metrics (DLP, CTDI, and predicted effective dose), indicating standard protocols are applied uniformly to both male and female patients. This uniformity provides reassurance and suggests that current imaging protocols are equally effective for both genders.In the subset of patients with both preoperative and postoperative radiation data, we observed an increase in radiation parameters postoperatively. Although these increases were not statistically significant, likely due to the limited sample size, they highlight the potential for cumulative radiation exposure. This finding underscores the need for careful consideration and judicious use of postoperative imaging to avoid unnecessary radiation exposure. Cone Beam CT (CBCT) offers a viable alternative to conventional TBCT, with significant potential for reduced radiation doses in postoperative CI imaging [18]. Furthermore, reducing the radiation dose of standard protocols is feasible, as no correlation was observed between artifact size and the administered radiation dose [18].Radiation sensitivity and the risk of cancerous changes are not only dependent on the radiation dose received, but several other factors also play a role in this phenomenon including age and gender. Children are more susceptible to radiation-induced cancer and genetic mutations due to their rapidly dividing cells and immature immune systems [7, 8]. Furthermore, children's developing organs are more sensitive to radiation than adults [19, 20]. Moreover, as the time after exposure to radiation increases, the probability of developing cancer caused by the radiation also increases. This can be explained by the cumulative effect of radiation on the cells over time [21, 22]. Furthermore, gender is an essential factor to consider in the context of radiation exposure. Females were found to be more radiosensitive compared to males [23]. A previous study provided evidence that CT-related radiation exposure increases the risk of brain tumors, although no association with leukemia was observed [24]. However, our follow-up data did not show any cases of cancer or other radiation-related illnesses in the cohort, which is reassuring. However, it is critical to recognize the relatively short follow-up period. The long-term effects of radiation exposure, particularly the risk of stochastic effects such as cancer, may not become evident until 20 to 40 years post-exposure. This latency underscores the importance of minimizing radiation exposure whenever possible, especially in pediatric populations. Although limited studies have reported specific adverse effects from TBCT radiation exposure in children, it is crucial to consider the potential long-term effects of ionizing radiation.

CI patients may be exposed to high levels of radiation due to repeated CT scans, increasing the risk of stochastic effects. The findings of this study emphasize the importance of continuous monitoring and optimization of radiation doses in pediatric patients undergoing TBCT scans. Given the vulnerability of pediatric patients to radiation-induced risks, it is imperative to adhere to the ALARA (As Low As Reasonably Achievable) principle [12]. This study provides a foundation for developing age-specific and indication-specific guidelines to further reduce radiation exposure without compromising diagnostic efficacy. while our findings indicate adherence to standardized radiation protocols and no immediate adverse health effects, the potential long-term risks underscore the necessity for ongoing monitoring and judicious use of CT scans in this vulnerable population. Our study emphasizes the importance of minimizing radiation exposure, particularly through the cautious use of postoperative imaging, to mitigate any potential long-term stochastic effects.The study has encountered several limitations. The limited number of postoperative TBCT dose reports led us to rely on the preoperative doses to predict radiation exposure.

However, the study serves a crucial purpose in shining the light on a subject that has not been addressed in the literature. Considering these limitations, further research with a larger population and accurate reporting of postoperative effective doses are required. This study provides valuable insights into the pre-operative and post-operative radiation exposure in pediatric patients undergoing TBCT scans for cochlear implantation over a decade. The findings reveal important trends and correlations in radiation dose parameters, which have significant implications for clinical practice and patient safety. The cumulative radiation exposure from multiple TBCT scans over a short duration raises concerns for pediatric CI patients. Although the amount of radiation exposure from a TBCT scan is relatively low, the healthcare provider should always weigh the risks and benefits of medical imaging, while acknowledging the long-term effects of high radiation exposure, especially in children. Imaging studies should only be ordered when necessary, and efforts should be made to minimize radiation exposure whenever possible. The adoption of already established low-dose TBCT protocols or CBCT should be considered in order to minimize the amount of radiation exposure with the preservation of the image quality and patient safety. Furthermore, alternatives to preoperative TBCT should be considered by utilizing the CBCT or settling for preoperative MRI because postoperative CT sometimes cannot be avoided due to unexpected postoperative complications.

6. Conclusion

This study underscores critical aspects of radiation exposure in pediatric patients undergoing TBCT scans for cochlear implantation. It demonstrates that these patients frequently undergo repeated TBCT scans in short intervals, resulting in higher radiation exposure. This finding emphasizes the importance of adhering to standardized radiation protocols to minimize exposure, particularly in pediatric cochlear implant patients. While no immediate adverse health effects were observed, the potential long-term risks necessitate ongoing vigilance. Clinicians should continue to critically evaluate the necessity of each CT scan and consider alternative imaging modalities with lower radiation exposure when feasible. Future research should focus on long-term follow-up to better understand the potential stochastic effects of radiation exposure in this population and to refine guidelines for imaging practices in pediatric CI patients.

7. Ethical Approval

The research has received approval from the Institutional Review Board at the College of Medicine, King Saud University (Ref. No. 23/0295/IRB). The research adhered rigorously to the ethical principles set out in the Declaration of Helsinki.

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