Is Radiation exposure during sacral neuromodulation within safety limits?

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Introduction

- The U.S. Food and Drug Administration (FDA) approved Sacral Neuromodulation (SNM) for intractable urge incontinence in 1997, urgency/ frequency syndrome, and non-obstructive urinary retention in 1999 for Patients who have failed to respond or could not tolerate conservative treatment [1].
- In 2011, the FDA approved SNM for chronic fecal incontinence in patients who have failed or could not tolerate conservative treatment.
- Fluoroscopy guidance is recommended during permanent tined lead insertion in to S3 foramen . Fluoroscopy utilizes X-rays ,which are high energy ionizing radiations which causes cellular damage and even cell death. The amount of damage depends upon the total dose, duration of exposure, and the site of exposure. This damage can lead to biological effects, which may be stochastic (independent of the dosage received) or deterministic (dose-dependent effects) [2,3]. The major source of radiation is the C-arm, which is used to produce images for surgical guidance.

Aims of study

To measure patient's radiation exposure during Neurostimulator Implantation and to know if the radiation exposure within the safety radiation exposure limits?

Study design, materials and methods

Retrospectively we reviewed medical charts of patients who underwent Interstim implantation performed by one surgeon, his trained fellows, or residents between January 2014 and July 2016. We obtained the approval from the Research Ethic Board of the UHN # 16-5889-AE. Patient's demographic data, Body mass index (BMI), indication of treatment, radiation dose data (fluoroscopy time (FT), cumulative dose (CD) which also known as air kerma at the patient entrance reference point (usually measured in mGy), and dose area product (DAP) which also known as kerma area product (usually measured in Gy.cm2)), the nature of surgery and operation time were collected. We compared our results to guidelines approved in 2009 by Society of Interventional Radiology (SIR) and Cardiovascular & Interventional Radiology Society of Europe (CIRSE) which identify patients with potential skin injuries requiring clinical follow-up (peak skin dose > 3 Gy, air kerma at the patient entrance reference point >5 Gy, kerma area product >500 Gy·cm2, or fluoroscopy time >60 minutes)[4].

Results

141 medical charts were reviewed, 83 patients were included in our study, and 58 patients were excluded due to insufficient radiation dose data. Female were the majority (67.5%), Mean age was 58.3 years (range 21-86 years, SD 14), Mean BMI was 28.9 kg/m^2 (SD 6).Indication of treatment as follows: Overactive bladder syndrome(50.6%), Idiopathic urinary retention (36.2%), Painful bladder syndrome (7.2%),Fecal incontinence (4.8%), and Nocturnal enuresis (1.2%).Full implantation was the most common surgery (47%) followed by stage implantation (34.9%), Revision (17%), and Twin implantation (1.2%). The mean operation time was 37.16 minutes (21-69 min, SD 10). The FT was measured in 83 patients: the mean FT was 31.03 seconds (9.5 -155 sec, SD 20). The CD was measured in 50 patients: the mean CD was 13.36 mGy (2.11-33.11 mGy, SD 9).DAP was measured in 33 patients, mean DAP 3.97 Gy.cm^2 (0.5995-24.93 Gycm^2, SD 4).

Interpretation of results

- Following guidelines approved in 2009 by SIR and CIRSE which identify patients with potential skin injuries requiring clinical follow-up, FT, CD and DAP during interstim implantation were far away minimal from guidelines thresholds(peak skin dose > 3 Gy, air kerma at the patient entrance reference point >5 Gy, kerma area product >500 Gy·cm2, or fluoroscopy time >60 minutes).

Concluding message

- Patient's radiation exposure during interstim implantation is safe according to the norms of the Society of Interventional Radiology (SIR) and the CRSE.

Limitation

- Retrospective study and small number of patients

Disclosure

- No relevant financial or nonfinancial relationships to disclose.

References

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