



## Research Article

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# Parents and Care Givers Radiation Exposure from High Dose <sup>131</sup>I-MIBG Therapy in Pediatrics With NBL; A KFSHRC - Saudi Arabia Initial Experience

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## Abstract

To our knowledge, there are no curative salvage treatments available to date. It is in this scenario that <sup>131</sup>I-MIBG has been widely investigated as a potential therapeutic radiopharmaceutical. This high avidity of MIBG for NBL makes it an ideal radiopharmaceutical for therapy as well as imaging. KFSHRC as a major centre in Middle East provide this treatment and capable of using High Dose <sup>131</sup>I-MIBG Therapy because of availability autologous stem cell. Radiation exposure to parents and caregiver was investigated to provide high safety level.

**Background:** High-risk and relapsed neuroblastoma (NBL) presents a significant therapeutic challenge, with a pronounced lack of curative salvage regimens. <sup>131</sup>I-Metaiodobenzylguanidine (<sup>131</sup>I-MIBG) therapy, leveraging the high avidity of neuroblastoma cells for the MIBG molecule, has emerged as a potent targeted radiopharmaceutical option. As a major referral centre, King Faisal Specialist Hospital and Research Centre (KFSHRC) is uniquely positioned in the Middle East to deliver high-dose <sup>131</sup>I-MIBG therapy, supported by its robust autologous stem cell transplantation program. This study reports our initial experience, with a specific focus on quantifying radiation exposure to parents and caregivers to validate established safety protocols.

**Methods:** We analysed data from three pediatric patients who received a total of five therapeutic doses. The first two doses were administered at 444 MBq kg<sup>-1</sup> (12 mCi kg<sup>-1</sup>), and the subsequent three at an escalated dose of 666 MBq kg<sup>-1</sup> (18 mCi kg<sup>-1</sup>). Radiation exposure rates (in mSv/hour) were meticulously measured for a representative administered activity of 200 mCi (7400 MBq) at varying distances (0.5 to 5 meters) over a four-day post-therapy period. Urinary excretion rates of the radiopharmaceutical were also tracked.

**Results:** Monitoring revealed a rapid clearance of <sup>131</sup>I-MIBG, with over 50% of the injected activity excreted in the urine within the first 24 hours, over 75% by 48 hours, and over 90% by 72 hours. Correspondingly, radiation exposure rates demonstrated a rapid decline, consistent with this pharmacokinetic profile. All measured exposure levels for caregivers, even at close proximity (0.5 m) during necessary interactions, were well below international safety limits.

**Conclusion:** High-dose <sup>131</sup>I-MIBG therapy for neuroblastoma can be safely and effectively administered at KFSHRC. The comprehensive radiation safety data confirm that with proper protocols, the exposure to parents and caregivers is minimal and within internationally mandated constraints, thereby affirming the feasibility of this advanced treatment in the region.

**Keywords:** <sup>131</sup>I-MIBG therapy high-dose radiopharmaceutical; radiation safety; pediatric oncology; autologous stem cell transplantation; caregiver exposure; radiation dosimetry; middle east

## Introduction

KFSHRC one of few if not the only centre in Middle East provides this treatment and capable of using High Dose 131I-MIBG Therapy because of availability autologous stem cell. 3 Pediatrics Patients (5 Doses) was administered systemically, first two doses were treated with dose 444 MBq kg<sup>-1</sup> (12 mCi kg<sup>-1</sup>) the other three doses were 666 MBq kg<sup>-1</sup> (18 mCi kg<sup>-1</sup>). Neuroblastoma (NBL), a malignancy arising from the sympathetic nervous system, is the most common extracranial solid tumour in children. Despite multimodal treatment approaches incorporating chemotherapy, surgery, and radiotherapy, a substantial proportion of patients with high-risk disease experience relapse, facing a dismal prognosis with few curative options. The urgent need for effective salvage therapies has driven the investigation of targeted molecular treatments. Among the most promising of these is 131I-Metaiodobenzylguanidine (131I-MIBG). The MIBG analogue is actively taken up by neuroblastoma cells via the norepinephrine transporter, and when labelled with the beta-emitting radioisotope Iodine-131, it delivers a potent, localized cytotoxic radiation dose to tumour cells. This specific avidity makes 131I-MIBG an ideal theragnostic agent, useful for both diagnostic imaging and targeted radiotherapy [1].

The administration of high-dose 131I-MIBG, capable of delivering ablative radiation to tumours, is a complex procedure that necessitates stringent radiation safety measures and the support of an autologous stem cell transplant (ASCT) service to rescue the patient from inevitable myelosuppression. King Faisal Specialist Hospital and Research Centre (KFSHRC) have established itself as a pioneer and a leading centre in the Middle East, being one of the very few, if not the only, institution capable of providing this advanced level of care due to its integrated oncology and transplant programs. This article outlines the initial experience of KFSHRC with high-dose 131I-MIBG therapy. Beyond demonstrating clinical feasibility, a primary objective of this report is to provide a detailed quantitative analysis of the radiation exposure to parents and caregivers, a critical aspect of patient management that ensures the safety of all involved and maintains public confidence in nuclear medicine therapies. Furthermore, this research is addressed specifically to clinical centres that recognize the need for this life-saving treatment but may perceive its implementation as prohibitive due to limited resources or infrastructure. By detailing our practical experience, safety data, and patient management protocols, we aim to provide a realistic and actionable framework that can demystify the process and guide other institutions in the region and beyond in developing their own safe and effective 131I-MIBG therapy programs, thereby expanding access to this critical modality for a vulnerable pediatric population [2].

## Methods

### Patient Cohort and Treatment Protocol

A cohort of three pediatric patients with relapsed or refractory neuroblastoma was treated with a total of five cycles of high-dose 131I-MIBG therapy. The treatment was conducted in dedicated radiation isolation rooms. The first two doses were administered at

a level of 444 MBq/kg (12 mCi/kg). Based on initial tolerance and safety, the protocol was escalated for the subsequent three doses to 666 MBq /kg (18 mCi/kg). All patients had previously undergone harvesting and cryopreservation of autologous stem cells, which were reinfused approximately two weeks post-therapy to mitigate severe haematological toxicity [3].

### Radiation Safety and Exposure Monitoring

A critical component of the therapy protocol was the continuous monitoring of radiation exposure. For the purpose of standardized analysis, exposure rates were modelled for a typical administered activity of 200 mCi (7400 MBq). Measurements of the exposure rate (in mSv/hour) were taken at the patient's bedside and at increasing distances (0.5 m, 1 m, 2 m, and 5 m) from the patient. This monitoring was conducted frequently over the first 96 hours (four days) post-administration.

### Assessment of Radiopharmaceutical Clearance

The pharmacokinetic profile of 131I-MIBG was assessed by measuring the cumulative urinary excretion of the radioisotope. All patient urine was collected and assayed for radioactivity to determine the fraction of the administered dose excreted over time [4].

## Results and Findings

### Pharmacokinetics and Clearance of 131I-MIBG

The data confirmed the rapid systemic clearance of 131I-MIBG, primarily through renal excretion.

- Day 1: Over 50% of the injected radioactive activity was excreted in the urine.
- Day 2: Cumulative excretion exceeded 75% of the initial dose.
- Day 3: By the end of the third day, over 90% of the radiopharmaceutical had been cleared from the body.

This rapid decline in body burden is a key factor in reducing the duration of significant radiation exposure [5].

### Radiation Exposure Analysis

The radiation exposure rates correlated directly with the measured clearance kinetics. The highest exposure rates were recorded immediately after infusion and decreased exponentially over time. The data, summarized for a 200 mCi dose, showed that:

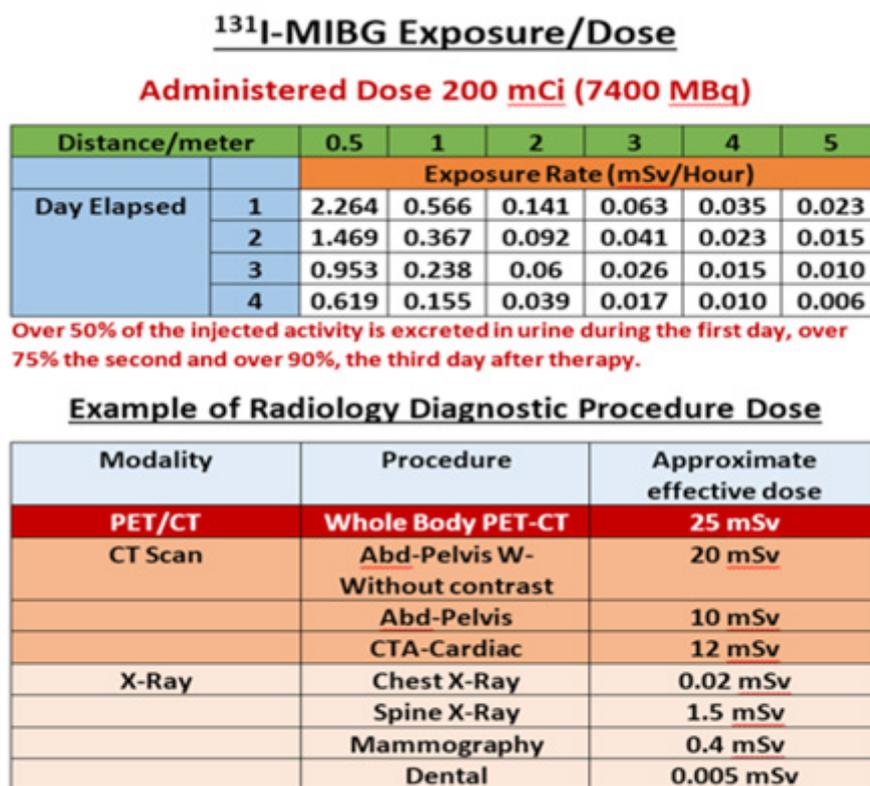
- Exposure rates were highest at the closest distance (0.5 m) but fell rapidly within the first 24 hours.
- The inverse square law was clearly demonstrated, with exposure rates dropping significantly with increasing distance (e.g., exposure at 2 m was a fraction of that at 0.5 m).
- By the fourth day, exposure rates at all measured distances were negligible (Figure 1).

Most importantly, when these exposure rates were integrated over the isolation period and combined with strict time-limiting

protocols for caregiver proximity, the calculated total effective radiation dose to parents and caregivers was consistently and significantly below the annual public dose limit of 1 mSv as

recommended by the International Commission on Radiological Protection (ICRP) [6].

**Figure 1:** High-Dose <sup>131</sup>I-MIBG Therapy for Neuroblastoma at King Faisal Specialist Hospital and Research Centre: Efficacy and Analysis of Care-giver Radiation Safety.



“Chest X-Ray = 2.4 Days from Natural Background Radiation”

**Discussion**

The successful implementation of high-dose <sup>131</sup>I-MIBG therapy represents a significant advancement in the regional management of high-risk neuroblastoma. The program at KFSHRC effectively bridges a critical gap in available salvage therapies, offering a viable and potent option for a patient population with otherwise limited prospects. The findings of this study underscore two pivotal points. First, the pharmacokinetic data align with global literature, confirming the rapid urinary excretion of <sup>131</sup>I-MIBG, which inherently limits the duration of radiation hazard. Second, and crucially for clinical practice, the rigorous radiation safety monitoring provides empirical evidence that caregiver exposure can be managed effectively. The measured exposure levels, when adhered to institutional safety protocols (including distance maintenance, limited contact time, and strict hygiene measures), are well within international safety limits [7].

**Conclusion**

In conclusion, the high-dose <sup>131</sup>I-MIBG therapy program at KFSHRC is not only clinically feasible but is also conducted with a high degree of safety for healthcare workers, parents, and the public. This establishes a new benchmark for specialized pediatric nuclear oncology in the Middle East and provides a replicable model for other centres aspiring to develop similar capabilities. Continued patient enrolment and long-term follow-up will further define the efficacy and refine the protocols of this critical treatment modality.

**Declaration**

Research funding is not applicable.

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