Performance Evaluation of the ^{177}Lu Removal Device "BSL-177": Initial Study

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2025年11月30日論文受領、修正依頼2025年12月10日、最終受理2025年12月13日

【要旨】核医学治療におけるルテチウム-177(^{177}Lu)製剤の使用増加に伴い、高濃度放射性排出物(主に尿)の管理が喫緊の課題となっている。従来の貯留・減衰処理では、病床・貯水槽の不足から投与可能量の制限や、大規模な設備拡張が必要となる。本研究では、ポータブルな放射性排水処理システム「BSL-177」の有効性を評価した。^{177}Lu-oxodotreotide治療を受けた患者3名の畜尿検体(投与後15.8 ～ 21.9時間)をBSL-177で処理した結果、放射能除去率が99.47 ～ 99.95%と、すべて99%以上だった。BSL-177は、特別な工事が不要で導入が容易であり、従来の受動的な減衰プロトコルに代わる能動的な処理システムとして、貯水槽への負担を大幅に軽減できる。これにより、高濃度放射性尿を長期保管する必要がなくなり、感染性廃棄物管理や被ばくリスクを低減できる。BSL-177は、核医学治療の円滑な提供と、医療施設における放射線安全管理強化を両立させる、有効な解決策となりえる。

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【キーワード】^{177}Lu-DOTATATE, Neuroendocrine tumor, radio waste, urine, radioactive material removal
【利益相反】Yuichiro Sugawara and Yasuko Kikuchi are employees of Advanced Medical Science-Planning, Inc.
Kenji Hirata receives research funding from Advanced Medical Science-Planning, Inc.
【グラント】なし

【Abstract】The increasing use of Lutetium-177 (^{177}Lu) radiopharmaceuticals in targeted radionuclide therapy necessitates effective management of high-concentration radioactive excreta, primarily urine. Conventional protocols relying solely on storage and decay often lead to limitations in the administered radioactivity due to insufficient hospital beds and drainage tank capacity, frequently requiring costly infrastructure expansion. This study evaluated the efficacy of BSL-177, a portable radioactive wastewater adsorption system. Urine samples (collected 15.8–21.9 hours post-administration) from three patients who received ^{177}Lu-oxodotreotide treatment were processed using BSL-177. The results showed a high radionuclide removal efficiency, ranging from 99.47% to 99.95% across all cases. BSL-177 is a facile, active processing alternative to passive decay protocols, requiring no special construction for installation and significantly reducing the load on storage tanks. This eliminates the need for long-term storage of highly radioactive urine, thereby mitigating risks associated with infectious waste management and radiation exposure. The BSL-177 system presents a viable solution for both facilitating the smooth provision of targeted radionuclide therapy and enhancing radiation safety in medical facilities.

[Introduction]

In recent years, the field of targeted radionuclide therapy has emerged as a crucial pillar of cancer treatment. In particular, with the increasing clinical use of therapeutic radiopharmaceuticals utilizing Lutetium-177 (^{177}Lu), such as ^{177}Lu-oxodotreotide[1,2] and ^{177}Lu-PSMA-617 [3-5], medical facilities must prepare to provide these treatments. Traditionally, targeted radionuclide required patient isolation in shielded radiotherapy rooms to manage radioactive wastewater and exhaust. However, since ^{177}Lu preparations release very little radioactive material into the exhaust air [6,7], treatment can be conducted in authorized specialized rooms (special measures patient rooms) [8], and the shortage of hospital beds is gradually improving. Nevertheless, the management of high-concentration radioactive excreta remains an urgent issue for radiation safety management in medical facilities [9].

^{177}Lu has a physical half-life of 6.7 days, and its excreta possesses different characteristics from short-lived diagnostic nuclides, necessitating effective disposal methods. ^{177}Lu is administered in a chelated state, and its excretion depends heavily on the patient's renal function and receptor binding affinity. In patients administered ^{177}Lu-oxodotreotide or ^{177}Lu-PSMA-617, most of the substance is excreted in the urine. Quantitative data indicate that approximately 70% of the total administered radioactivity is excreted from the body via urine, primarily within the first 24 hours post-administration[10,11]. Radioactive wastewater is temporarily stored in storage tanks (decay tanks) via septic tanks and discharged into the general sewage system after decay or dilution. However, if storage tank capacity is insufficient, reliance solely on conventional protocols of storage and decay limits the amount of ^{177}Lu radioactivity that can be administered. Furthermore, installing new storage tanks or expanding existing ones is often difficult due to space and cost constraints. While methods exist to store urine for decay through solidification or freezing without discharging it into the controlled area drainage system, these approaches present challenges regarding storage space, necessary equipment, and radiation exposure during processing. This situation strongly suggests the need for active processing systems rather than passive decay protocols that depend solely on physical half-life. Among active processing systems, advanced adsorption technology is attracting attention as the most sustainable solution for ^{177}Lu excreta management.

"BSL-177" is a portable radioactive wastewater treatment system capable of adsorbing and recovering ^{177}Lu from excreted urine using a relatively small column. Its introduction requires no special construction work, and it eliminates the need to discharge patient urine directly into storage tanks, thereby minimizing the load on such infrastructure. In this study, we evaluated the ^{177}Lu removal performance of BSL-177 using urine from patients administered ^{177}Lu-oxodotreotide.

[Materials and Methods]

This prospective observational study was conducted with the permission of the Director of Hokkaido University Hospital, following approval by the Hokkaido University Hospital Institutional Review Board (Approval No. SEI: 024-0262). Written informed consent was obtained from all patients using an explanation document.

Subjects and Samples

The study targeted patients aged 18 years or older scheduled for 177Lu-oxodotreotide therapy for unresectable somatostatin receptor-positive neuroendocrine tumors at our hospital. Patients who did not consent or were deemed inappropriate due to complications or their treatment course were excluded. Urine collection was performed from the time of ^{177}Lu-oxodotreotide administration until the end of isolation or 24 hours post-administration, whichever occurred first.

Treatment Protocol

Administration was performed according to the standard method described in the package insert. Granisetron was intravenously administered over 30 minutes, 1 hour prior

Figure 1. Appearance of BSL-177.
The BSL-177 unit measures 900 mm (W) × 500 mm (D) × 850 mm (H), weighs approximately 150 kg, and requires a power supply of 100V AC, 50/60 Hz, rated within 1500W.

Table1. Patients' characteristics

No	Age	Sex	BMI (kg/m^2)	eGFRcreat (ml/min)	Primary tumor	Ki-67 (%)	Metastases	PRRT Number (n)
1	70's	Male	19.3	59.5	Lung	About 20	Liver, Lung, Bone	1
2	60's	Male	22.8	68.6	Pancreas	3.3	Liver	4
3	50's	Male	24.8	66.9	Rectal	<1	Liver, Bone	4

BMI, body mass index; PRRT, peptide receptor radionuclide therapy

Table2. Results of the adsorption by BSL-177

No	Administered dose (MBq)	Urination time (h)	Excretion radioactivity (MBq)	Excretion radioactivity ratio (%)	Pre-adsorption volume (mL)	Pre-adsorption radioactivity (MBq)	BSL-177 Work Hours (h)	Post-adsorption radioactivity (MBq)	Radioactivity Removal Rate (%)
1	7236.5	15.8	2815	38.9	2695	2214	19.0	10.42	99.53
2	7072.1	21.9	5690	80.5	2366	5266	17.1	2.69	99.95
3	7165.4	21.0	5658	79.0	2492	4873	22.2	25.88	99.47

to ^{177}Lu-oxodotreotide (Lutathera®, Novartis Pharma) administration. Subsequently, 1000 mL of lysine/arginine infusion (LysaKare®, Novartis Pharma) was intravenously administered over 4 hours for renal protection. Thirty minutes after the amino acid infusion started, 7.4 GBq of ^{177}Lu-oxodotreotide was administered intravenously over at least 30 minutes using the gravity drip method. Patients were isolated in a radiotherapy room or a special measures patient room immediately after the start of administration.

The "BSL-177" System

The external appearance of the device is shown in **Figure 1**. The BSL-177 unit measures 900 mm (W) × 500 mm (D) × 850 mm (H), weighs approximately 150 kg, and requires a power supply of 100V AC, 50/60 Hz, rated within 1500W. A lead-shielded space (6 sides) at the bottom of the main unit houses the urine collection container, the adsorption column, and an empty container for storing the processed urine. The disposable column is approximately 30mm in diameter × 150mm in length and is replaced after processing the pooled urine from one patient. Liquid transfer is performed automatically via a single switch to conduct adsorption processing. The processing speed is 5–10 mL/min, with almost no noise generated during operation. The collected urine samples were processed using the BSL-177 adsorption column at a rate of 5–10 mL/min to remove radionuclides.

Sample Measurement

Aliquots were sampled from the urine before and after removal. The ^{177}Lu radioactivity was measured using a calibrated dose calibrator, and the total radioactivity before and after removal was calculated. The removal rate was determined from the radioactivity levels before and after processing.

[Results]

The characteristics of the subjects are shown in **Table 1**. The analysis included three male patients. Case No. 1 presented with a pulmonary atypical carcinoid with a Ki-67 index of approximately 20%. Following resection of the primary tumor, multiple metastases appeared in the lymph nodes, lungs, bone and liver. The patient underwent cisplatin and etoposide as first-line therapy, everolimus as second-line, amrubicin as third-line, and carboplatin and etoposide as fourth-line therapy, before commencing ^{177}Lu-oxodotreotide as fifth-line therapy. Case No. 2 had a pancreatic neuroendocrine tumor (WHO grade 2) with synchronous multiple liver metastases. First-line therapy with everolimus plus lanreotide resulted in disease progression, leading to the initiation of ^{177}Lu-oxodotreotide as second-line therapy. Case No. 3 had a rectal neuroendocrine tumor (WHO grade 1) with synchronous multiple liver metastases. Disease progression occurred after first-line everolimus and second-line lanreotide, leading to the initiation of ^{177}Lu-oxodotreotide as third-line therapy. The treatment cycles evaluated in this study were the 1st, 4th, and 4th cycles for the respective patients. Renal function, estimated glomerular filtration rate from blood tests on the day prior to ^{177}Lu-oxodotreotide administration, was 59.5 mL/min, 68.6 mL/min, and 66.9 mL/min, respectively, all within the normal range. Whole-body planar scintigraphy images obtained after ^{177}Lu-oxodotreotide administration are shown in **Figure 3**.

Table 2 presents the results regarding the collected urine samples and removal efficiency by BSL-177. All radioactivity values were decay-corrected to the time of ^{177}Lu-oxodotreotide administration.

The urine collection time ranged from 15.8 to 21.9 hours, with the total collected volume spanning 2366 to 2695 mL. The total radioactivity excreted in the urine was 2214 to 4873 MBq, and

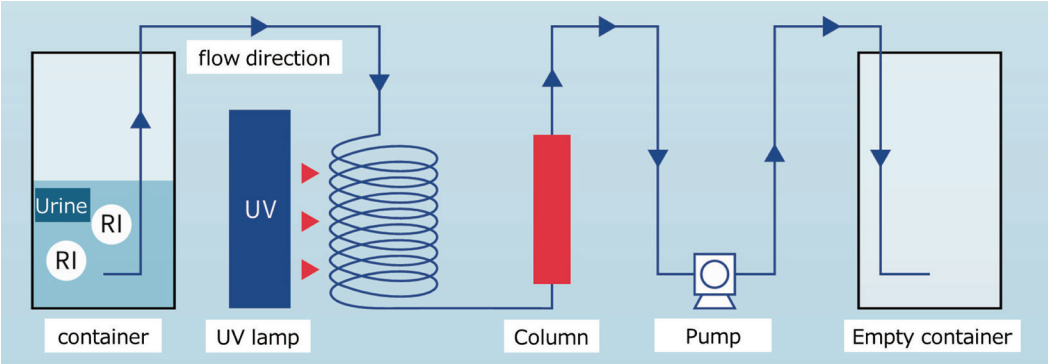

Figure 2. Schematic diagram of the BSL-177 system.
Urine from the collection container is pumped into the column, where radionuclides (RI) are adsorbed. The processed urine then flows into an empty container. Only the column containing the adsorbed RI requires replacement and disposal. UV; ultraviolet.

the percentage of administered radioactivity excreted in the urine ranged from 38.9% to 80.5%. Although not all collected urine was processed by BSL-177 due to the disposal of some samples for measurement, the removal processing time using BSL-177 was 17.1 to 22.2 hours. The radioactivity remaining in the urine after processing was 2.69 to 25.88 MBq, resulting in a radioactivity removal efficiency of 99.47% to 99.95%.

[Discussion]

In urine samples collected 15.8 to 21.9 hours after ^{177}Lu-oxodotreotide administration, the urinary excretion rate of radioactivity was 38.9%–80.5%. Adsorption processing using BSL-177 over 17.1–22.2 hours achieved removal rates of 99.47%–99.95%, successfully reducing urinary radioactivity to less than 1%.

While dose reduction equivalent to 99% decay of ^{177}Lu typically requires approximately 44 days (over 1000 hours), the BSL-177 system completed the process in approximately 20 hours of operation, running from the end of urine collection until the following morning or afternoon. Storing high-concentration radioactive urine until it decays requires addressing issues related to infectious waste, hygiene management, and space allocation. In contrast, the BSL-177 device is compact and requires no special construction or renovation for installation. It eliminates the need for large-scale construction to install or expand storage tanks and is easily introduced into general hospitals. The operation requires only changing the cap of the urine collection bottle, setting the inflow tube, and turning on the switch, all of which can be completed in less than one minute.

The introduction and dissemination of ^{177}Lu-oxodotreotide and ^{177}Lu-PSMA-617 in Japan remain insufficient. Mizowaki et al. reported that simulations based on the Japanese model predict a significant backlog of patients awaiting targeted radionuclide therapy [9]. While increasing the number of radiotherapy rooms and special measures patient rooms, as well as strengthening regional hospital collaborations, are necessary solutions, these alone are insufficient; the expansion of drainage systems is also cited as a critical element. While expanding drainage infrastructure requires significant resource investment, this device offers an alternative solution by reducing the load on storage tanks. Although the task of urine collection is still required, the system minimizes the risks of environmental and public exposure caused by the accidental discharge of urine containing high-concentration radioactivity into general drainage systems.

Furthermore, it facilitates cost reduction in radioactive waste management, reduces workload, and simplifies regulatory compliance. The enhancement of radiation protection measures also provides the added benefit of increasing the peace of mind of medical staff. It is also anticipated that by integrating advanced technology like this device into operational standards, the institutional capacity for patient intake can be expanded, thereby improving the overall supply capability of targeted radionuclide therapies. In the future, installation in outpatient settings could potentially expand options for outpatient targeted radionuclide therapy.

Although the removal rate exceeded 99% in this study, the evaluation was limited to three cases; therefore, continuous data collection is necessary to confirm validity and reproducibility. However, the mechanical design principle is simple—using a pump to flow urine from the collection container through an adsorption column—suggesting high reproducibility, durability, and ease of maintenance, with simple troubleshooting in

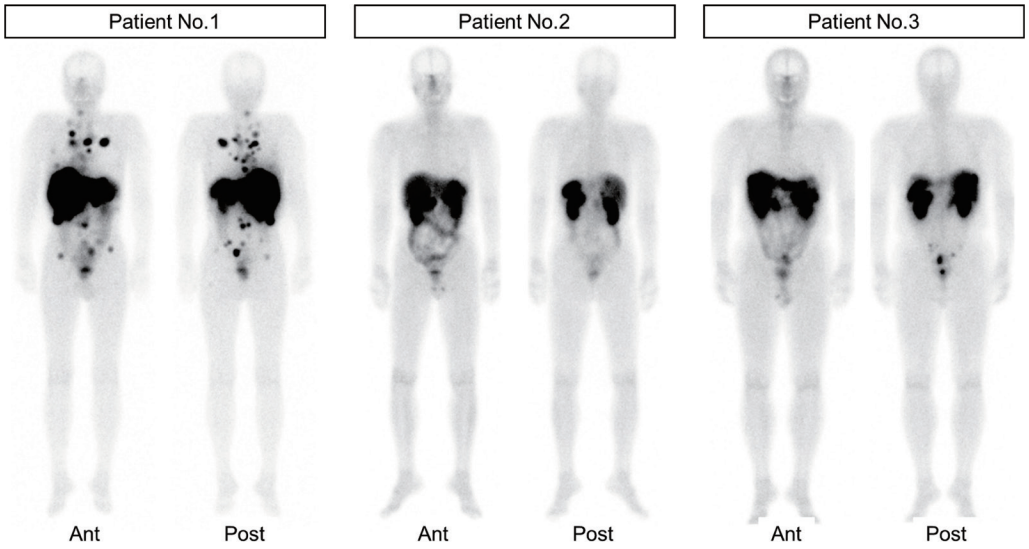

Figure 3. Post ^{177}Lu-oxodotreotide therapy planar scintigraphy for each case.
Patient No. 1 had a higher amount of residual radioactivity in the body compared to the other two cases.

the event of malfunction. Additionally, measurements were performed on the premise that the adsorbed nuclide was ^{177}Lu, without assuming the presence of other nuclides or ^{177m}Lu contamination. Therefore, the adsorption rates for other nuclides or agents other than ^{177}Lu-oxodotreotide remain unknown. As ^{177}Lu-PSMA-617 utilizes a ^{177}Lu-labeled preparation with a similar chelator, it is anticipated that the adsorption rate would not differ significantly.

A significant variation in the urinary ^{177}Lu excretion rate was observed among the three cases. While two cases showed excretion rates of approximately 80%, one case showed 38.9%, roughly half that of the others. Since excretion of ^{177}Lu-oxodotreotide is largely completed within 24 hours and renal function was within the normal range for all patients with no significant differences, this variation is unlikely to be due to renal function. The ^{177}Lu-oxodotreotide remaining in the body after 24 hours is bound to normal or tumor tissues. Therefore, this difference in excretion is predicted to depend on the amount of binding to these tissues. Post therapeutic scintigraphy (**Figure 3**) also showed that Case No. 1 had a higher amount of residual radioactivity in the body compared to the other two cases. This suggests a strong relationship between the amount of excreted radioactivity and the uptake by tumors in the body. Wakabayashi et al. demonstrated a direct relationship between the total accumulated ^{177}Lu on scintigraphy and the external dose rate [12]; the amount of urinary ^{177}Lu excretion could serve as an indirect indicator. If tumor uptake can be evaluated, it could become a predictor of therapeutic efficacy, providing clinically useful data. Although this study involved a small number of cases and other confounding factors likely affect excreted radioactivity, further in-depth research on this clinical correlation is desired.

[Conclusion]

The radioactivity adsorption rate from collected urine after ^{177}Lu-oxodotreotide administration using BSL-177 was over 99% in all three cases studied. As BSL-177 can serve as an active alternative to passive methods such as storage and decay in tanks for radioactive wastewater management, it has the potential to become an essential element for nuclear medicine facilities. It facilitates the appropriate provision of nuclear medicine therapy while balancing patient safety through radiation management with public reassurance.

[Acknowledgments]

We would like to thank the nurses at the 5-2 Nurse Station of Hokkaido University Hospital, the assistants, and the patients for their cooperation in this study.

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