Case work-up and monitoring of systemic radionuclide therapies: A proposed 3-sheet excel format with integrated graph for implementation in a busy treatment set-up

Therapeutic nuclear medicine using targeted systemic radionuclides (RN) has seen rapid development over the last decade as a popular and preferred treatment modality in clinical oncology practice in view of its excellent tolerability and minimal adverse effects as compared to systemic chemotherapies. As a consequence, there has been an increasing routine therapeutic work burden in the centers with RN therapy facilities. The domain and practice of therapeutic nuclear medicine esp. Newer systemic RN therapies is way different than pure diagnostic work this fraternity is used to. Monitoring of single patient during multiple therapy cycles with multiple investigations at every cycle (both in-house and outside) and also long follow-up need huge amount of clinical data to be handled for each patient.[1-3] In a standard government/university center in a developing country, the expanding numbers of treatment procedures while in private setups working with at most 1–2 physicians, the enhanced burden of therapeutic work adds up in hardship and increase in the chance of error or negligence. In a major treatment center in India like ours, the standing average weekly systemic RNT statistics include 15–20 radioiodine therapy for thyroid carcinoma, 20–25 (^{177}Lu) Lu-DOTA-TATE PRRT, 5–8 (^{177}Lu) Lu-PSMA PRLT, in addition to^{131}I-MIBG therapy for neuroblastoma, pheochromocytoma, or paraganglioma and pain palliation therapies that vary as per the patient referral. A user-friendly generalized protocol framework is thus the need of the hour, which can be easily modified depending on need of each patient individually.

We herein present a 3-sheet Excel format with integrated graph for case work-up and follow-up of the systemic RN therapies that could be conveniently employed in a busy treatment setup. The format primarily has three main sheets:

a. Sheet 1 [Table 1a]: Case summary that includes four subheadings (i) baseline information of the patient (including name, age, sex, institutional Id, and final tissue diagnosis; presenting symptoms; treatment history), (ii) details of RN therapies administered previously (dose, date, cumulative dose), (iii) any untoward event or new symptom during/after the therapy, and (iv) special remarks
b. Sheet 2: [Table 1b]: Response assessment summary in three scales symptomatic response (and health-related quality of life assessment); biochemical tumor marker response; imaging response (both anatomical and functional imaging-based RECIST 1.1 and PERCIST assessment)
c. Sheet 3 [Table 1c]. Adverse effect assessment: Hematological and renal parameters and also liver function tests or some specific values such as thyroid function test monitoring in case of^{131}I-MIBG therapy.

A dummy case example with graphical representation is illustrated from the ^{177}Lu-DOTATATE PRRT employing the aforementioned format [Tables 1a-c].

We believe adoption of such format would greatly aid management and monitoring of all aforementioned data conveniently (salient history, dose records, three-dimensional response assessment, adverse effects, and survival records over time) including the trend of the parameters at the same time and also be a convenient mode of digital record keeping over long time, thus could play pivotal role in better global monitoring of the patient and decision-making by the treating physician.

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Conflicts of interest

There are no conflicts of interest.

Table 1a: Basic information of patient

1.Identification	Mr.ABC ,52 years/Male, Case of Pancreatic NET with nodal and hepatic metastasis	
2.Primary presentation	Diarrhoea 5-6 times a day	
	Abdominal discomfort	
3.Primary Surgery/treatment received	not yet operated i/v/o inoperable and metastatic disease	
4.Details of other therapies given	External Radiation therapy - Nil	
	Chemotherapy- Nil	
	Received inj octreotite LAR (SSA) 30 mg IM per month for 3 months	
B) Radionuclide Therapy Administration Record		
RP used -	Date of therapy	Dose Administered (in mCi)
1.177Lu-DOTATATE	05-12-2018	180mCi
2.177Lu-DOTATATE	02-03-2019	178mCi
3.177Lu-DOTATATE	29-05-2019	170mCi
4.177Lu-DOTATATE	02-09-2019	176mCi
Cumulative Dose		704mCi
C) Any untoward event during admission at isolation ward/after therapy with date		
Nil		
D) Special Remarks		
Nil		

Table 1b: Response assessment summary

A) Symptomatic response and QoL performance					
Primary tumour related symptoms (percentage improvement in symptom)	**Pre 1st therapy cycle**	**Pre 2nd therapy/post 1 cycles**	**Pre 3rd therapy/post 2 cycles**	**Pre 4th therapy/post 3 cycles**	**Post 4 therapy cycles 1st follow up**
Diarrhoea	0	20	30	50	100
Abdominal discomfort	0	40	60	80	80
Indigestion	0	20	50	50	80
Additional general symptoms:	Nil				
Any newly started symptom during therapy :	Nil				
Patients health status					
ECOG performance status (0 to 4)	1	0	0	0	0
Karnofsky scale (100-10)	80	80	90	100	100
Global health score (physical, social and emotional - 0 for worst to 100 for best)	30	40	50	80	80
Visual Analogue Scale (VAS) in case of skeletal pain (0 to 10)	Nil				
Weight of patient (in kg)	62	64	65	68	68
B) Biochmeical Response					
Tumour markers	**Pre 1st therapy**	**Pre 2nd therapy**	**Pre 3rd therapy**	**Pre 4th therapy**	**Post 4 therapy cycles 1st follow up**
Sr. Chromogranin A (ng/mL)	520	450	280	310	240
24hrs Ur5HIAA (mg/24hr)	12	10	4	2	2

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Table 1b: Response assessment summary

C) Imaging Response					
	Pre 1st therapy	**Pre 2nd therapy**	**Pre 3rd therapy**	**Pre 4th therapy**	**Post 4 therapy cycles 1st follow up**
Anatomical-CeCT based criteria (RECIST1.1) size in cm	size in cm	size in cm	size in cm	size in cm	size in cm
Pancreatic head lesion	4.50			3.00	
Peri-pancreatic LN	3			1.2	
Liver Seg VIII lesion	8 x 6			5 x 5	
	8.0			5.5	
Liver Seg II/III lesion	2.5 x 2.0			2.0 x 1.2	
	2.5			2.0	
Liver Seg IVb lesion	5.5 x 3.0			3.0 x 2.0	
	5.5			3.0	
Category of response				PR	
Functional PET/CT based criteria					
^{68}Ga-DOTATATE PET/CT	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**
Pancreatic head lesion	35 (4.5)	33 (4.0)	29 (3.8)	25 (3.6)	25 (3)
	35.0	33.0	29.0	25.0	25.0
Peri-pancreatic LN	30 (3)	28 (2.8)	26 (2.5)	27 (1.9)	24 (1)
	30.0	28.0	26.0	27.0	24.0
Liver Seg VIII lesion	32 (8)	30 (7)	28 (6)	26 (6)	24 (5)
	32.0	30.0	28.0	26.0	24.0
Liver Seg II/III lesion	24 (2.5)	22 (2.5)	22 (2)	21 (2)	18 (2)
	24.0	22.0	22.0	21.0	18.0
Liver Seg IVb lesion	26 (5.5)	24 (4.7)	24 (4.5)	26 (3.8)	24 (3)
	26.0	24.0	24.0	26.0	24.0
Category of Response			SD		PR
Other planar gamma/SPECT scans					
^{18}F-FDG-PET/CT	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**	**SUVmax values (and size in cm)**
Pancreatic head lesion	3.4 (4.5)	3.4 (4.0)	3.0 (3.8)	2.8 (3.6)	2.6 (3)
	3.4	3.4	3.0	2.8	2.6
Peri-pancreatic LN	1.7 (3)	1.2 (2.8)	1.5 (2.5)	1.2 (1.9)	1.5 (1)
	1.7	1.2	1.5	1.2	1.5
Liver Seg VIII lesion	4.5 (8)	4.5 (7)	4.2 (6)	3.8 (6)	3.5 (5)
	4.5	4.5	4.2	3.8	3.5
Liver Seg II/III lesion	3.7 (2.5)	3.8 (2.5)	3.5 (2)	3.5 (2)	3.3 (2)
	3.7	3.8	3.5	3.5	3.3
Liver Seg IVb lesion	2.9 (5.5)	3.1 (4.7)	2.7 (4.5)	2.5 (3.8)	2.2 (3)
	2.9	3.1	2.7	2.5	2.2
Category of Response			SD		PR

Table 1c: Monitoring of adverse effects

A) Haematological (CBC)

	Haemoglobin (g/dl)	TLC (per cm^3)	Platelet count (x1000/cm^3)
pre 1st therapy cycle	11.8	6175	170
14 Days after therapy1	11.2	5975	147
28 Days after therapy1	10.5	5922	138
42 Days after therapy1	10.8	6039	148
56 Days after therapy1	11.1	6151	157
70 Days after therapy1	11.6	6093	162
84 Days after therapy1	11.5	6178	165
pre 2nd therapy cycle	11.5	6100	160
14 Days after therapy2	11.1	5856	145
28 Days after therapy2	10.8	5559	135
42 Days after therapy2	11.4	6120	139
56 Days after therapy2	11.6	6223	151
70 Days after therapy2	12.1	6207	158
84 Days after therapy2	11.8	6115	168
pre 3rd therapy cycle	11.8	6,115	168
14 Days after therapy3	11.5	5,400	143
28 Days after therapy3	10.8	5320	133
42 Days after therapy3	11.2	5455	153
56 Days after therapy3	11.5	5560	157
70 Days after therapy3	11.1	5622	162
84 Days after therapy3	11.6	5744	168
Pre 4th therapy cycle	11.6	5744	165
14 Days after therapy4	11.1	5534	145
28 Days after therapy4	11.2	5060	141
42 Days after therapy4	11.5	5173	155
56 Days after therapy4	11.5	5510	164
70 Days after therapy4	11.6	5675	168
84 Days after therapy4	11.5	5711	160

B) Renal parameters (RFTs, GFR etc)

	Blood urea (mg/dl)	S.creatinine (mg/dl)	GFR (ml/min) with DTPA renogram
pre 1st therapy cycle	19	0.80	68
14 Days after therapy1	18	1	
28 Days after therapy1	20	0.8	
42 Days after therapy1	17	0.8	
56 Days after therapy1	18	0.7	
70 Days after therapy1	18	0.8	
84 Days after therapy1	19	0.9	
pre 2nd therapy cycle	18	0.8	67
14 Days after therapy2	18	0.9	
28 Days after therapy2	18	0.7	
42 Days after therapy2	17	0.8	
56 Days after therapy2	16	0.8	
70 Days after therapy2	18	0.7	
84 Days after therapy2	18	0.8	
pre 3rd therapy cycle	19	0.7	60
14 Days after therapy3	19	0.8	
28 Days after therapy3	18	0.8	
42 Days after therapy3	19	0.7	
56 Days after therapy3	19	0.8	
70 Days after therapy3	18	0.8	
84 Days after therapy3	18	0.8	
Pre 4th therapy cycle	18	0.7	63

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Table 1c: Monitoring of adverse effects			
14 Days after therapy4	19	0.9	
28 Days after therapy4	17	0.7	
42 Days after therapy4	18	0.6	
56 Days after therapy4	17	0.7	
70 Days after therapy4	19	0.8	
84 Days after therapy4	16	0.7	65

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