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Internal radiation dosimetry of orally administered radiotracers for the assessment of gastrointestinal motility

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HIGHLIGHTS

- Internal radiation dose estimates for radionuclide GI transit were calculated.
- The ICRP 30 GI tract model, MIRDOSE 3.1 & OLINDA/EXM 1.0 software applications were used.
- The calculated equivalent dose and effective dose for organs were reported.
- The radiation doses among ^{153}Sm, ^{111}In and ^{99m}Tc formulations were compared.
- The calculated doses were in good agreement with the ARSAC published values.

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ABSTRACT

Radionuclide imaging using ^{111}In, ^{99m}Tc and ^{153}Sm is commonly undertaken for the clinical investigation of gastric emptying, intestinal motility and whole gut transit. However the documented evidence concerning internal radiation dosimetry for such studies is not readily available. This communication documents the internal radiation dosimetry for whole gastrointestinal transit studies using ^{111}In, ^{99m}Tc and ^{153}Sm labeled formulations. The findings were compared to the diagnostic reference levels recommended by the United Kingdom Administration of Radioactive Substances Advisory Committee, for gastrointestinal transit studies.

1. Introduction

It is essential that any medical radiation exposure is justified and optimized before use. With increased public awareness of ionizing radiation effects, all imaging studies involving radiation must have commensurate risk and benefit assessments. It is therefore important to estimate the radiation dose received by a patient administered with any amount of a radiopharmaceutical.

Nuclear medicine investigations are regarded as the gold standard for the assessment of gastric emptying and gastrointestinal (GI) motility. A number of potential radionuclides can be used for this purpose, each with advantages and disadvantages of photon energy, physical half-life and radiation dosimetry. The main radionuclides that have been employed are Indium-111 (^{111}In) and Technetium-99m (^{99m}Tc) which are incorporated into non-absorbable forms for oral administration. An alternative radionuclide, Samarium-153 (^{153}Sm) in the form of resin-based formulation, has recently been developed and tested to assess whole gut motility in constipated patients (Yeong, et al., 2011, 2012). The advantages of ^{153}Sm include minimal radiation exposure to radiopharmacy staff, improved manufacturing and radioactive transportation, workflow and potentially

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wider global availability through local production using a research reactor, hence resulting in lower cost. There are currently 246 research reactors in operation worldwide according to the IAEA research reactor databases (International Atomic Energy Agency, 2014). Nevertheless, there is a lack of published information on the effective dose resulting from the oral administration of ^{153}Sm. Current literature states that for ^{153}Sm (used in scintigraphic studies of drug delivery), an oral ingestion of 1 MBq of ^{153}Sm delivers an effective dose of 0.7 mSv (Ahrabi et al., 1999a, 1999b, 2000; Awang et al., 1993; Fani et al., 2002; Marvola et al., 2004, 2008). However the basis for this estimation is untraceable.

Unlike radiation doses received from external sources such as medical imaging X-ray devices, internal dose cannot be directly measured. Doses from radiopharmaceuticals are normally calculated from standardized models, assumptions and procedures (Stabin, 1996). In general, the calculation of internal dose has been performed by summing the radiation absorbed in various target tissue, from a number of source organs that contain significant quantities of the radionuclide. In nuclear medicine, the most commonly used method for the calculation of internal dose estimates is that developed by the Medical Internal Radiation Dose (MIRD) Committee of the Society of Nuclear Medicine and Molecular Imaging (SNMMI), United States (Toohey et al., 2000). The MIRD schema uses a unique set of symbols and quantities to calculate the absorbed dose in specified target organs from radioactive decays that occur in source organs.

This communication describes the estimation of the radiation dose including target organ equivalent dose (H_T) and effective dose (E) from the orally ingested radionuclides, i.e. ^{99m}Tc, ^{111}In and ^{153}Sm used for GI transit scintigraphy, to provide clinicians and researchers the relative risks associated with in vivo clinical studies.

2. Materials and methods

The H_T and E for ^{99m}Tc, ^{111}In and ^{153}Sm were calculated using the MIRDOSE 3.1 and OLINDA/EXM 1.0 software (Vanderbilt University, Nashville, Tennessee, United States). The pharmacokinetic data were incorporated into the ICRP 30 GI tract model. The mathematical model and software which gave the best fitted results to the published dosimetry data for ^{111}In and ^{99m}Tc were then used to extrapolate the radiation dose for ^{153}Sm-labeled resin formulations.

2.1. MIRDOSE 3.1

MIRDOSE 3.1 internal radiation dose assessment software was obtained from the Oak Ridge Associated Universities, Tennessee, United States. This program performs internal radiation dose calculations using the medical internal radiation dosimetry (MIRD) method (Toohey et al., 2000).

The system computes the absorbed dose to each target organ and total body (expressed in mGy MBq^{-1} and rad mCi^{-1}), effective dose equivalent (H_T) and effective dose (E) per unit of administered activity (expressed in mSv MBq^{-1} and rem mCi^{-1}). The percentages of primary and secondary source organ that contributed to the target organ dose were also included.

The "Adult (70 kg)" mathematical phantom was chosen which represented a male adult with a standard size of 70 kg. For female adults, the choices of models provided were non-pregnant, 3-month, 6-month and 9-month pregnant. Only the "Adult Female – Non-pregnant" model was used in this study. The ICRP 30 GI tract model was used to obtain the residence time and kinetic data. Given a fraction of activity entering the stomach at time zero and knowledge of how much is absorbed from the small intestine, the cumulated activities in all segments can be calculated. In this study, labeled non-absorbable compounds (ion-exchange resin) were studied, and the assumption was made that the fraction of activity entering stomach was 1.0 and the fraction of activity absorbed from the small intestine was zero. Table 1 shows the parameters used in the GI tract model.

H_T and E were then calculated using the software. The equivalent dose attributed to different types of radiation (β, γ- and X-ray) was also calculated. Using the same phantom and kinetic model, the radiation dose given by the same formulation but labeled with different radionuclides, ^{111}In and ^{99m}Tc were calculated and the data were compared with ^{153}Sm.

2.2. OLINDA/EXM 1.0

OLINDA/EXM 1.0 internal radiation dose assessment software was used to calculate H_T and E for the administered formulation. As was the case for MIRDOSE 3.1, the internal radiation dose assessment was based on the mathematical formulism developed by the MIRD Committee of the SNMMI, United States (Loevinger et al., 1988). While MIRDOSE 3.1 was written in Microsoft's Visual Basic language and run under the Windows operating system, the OLINDA/EXM 1.0 was written in Java programming language. Similar to the methods in MIRDOSE 3.1, the internal radiation doses were calculated and compared.

2.3. ICRP 30 GI tract model

The mathematical model of the GI tract was developed based on the ICRP 30 GI model data (ICRP, 1979a, 1979b). The model describes the GI tract as a four compartmental model with first order, one-way flow between compartments, and one pathway to the blood stream from the small intestine, as shown in Fig. 1.

Table 1
Summary of parameters used in the mathematical model of the GI tract.

Model	**GI tract model, adult male and female**					
Route of entry	Oral consumption, passing through					
Fraction of activity absorbed	Fraction of activity enters stomach: 1.0 Fraction of activity absorbed by stomach: 0.0 Fraction of activity enters small intestine: 1.0					
Residence time (Bq h Bq^{-1})	**Male**			**Female**		
	^{153}Sm	**^{111}In**	**^{99m}Tc**	**^{153}Sm**	**^{111}In**	**^{99m}Tc**
Stomach contents	10.90	0.99	0.90	0.99	0.99	0.90
Small intestines contents	3.80	3.80	2.45	3.72	3.80	2.45
Upper large intestines contents	10.90	10.90	3.19	10.10	10.90	3.19
Lower large intestines contents	16.10	16.10	1.56	13.80	16.10	1.56

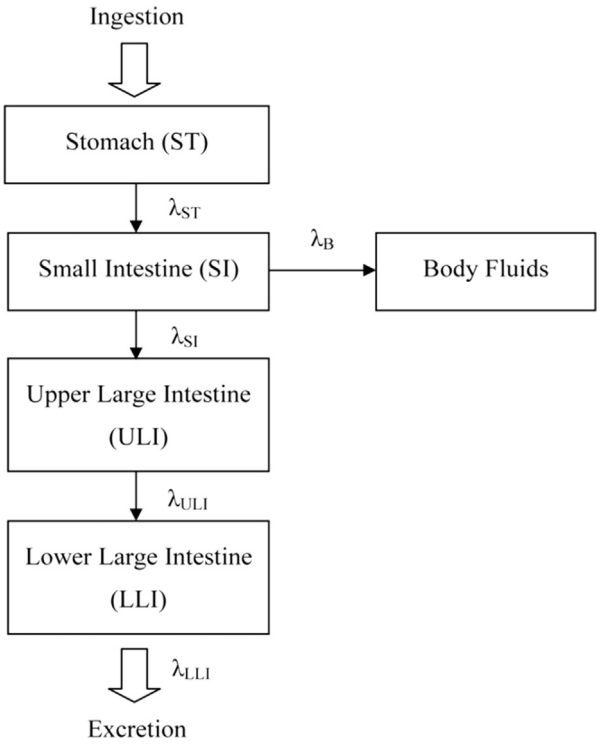

Fig. 1. Mathematical model used to describe the kinetics of radionuclides in the GI tract (adopted from the ICRP 30 GI model). λ= rate constant.

In this model, it is assumed that no absorption has taken place from the stomach and that material passes on to the next compartment with a mean residence time of 1 h. After the stomach, the mean residence time is taken to be 4 h in small intestine. This is the compartment from which absorption takes place. It is normal to quantify absorption by using the value $f1$, the fraction of material reaching body fluids following ingestion:

$$f_1 = \frac{\lambda_B}{\lambda_B + \lambda_{SI}}$$

where:

λ_B is the rate constant for transfer to body fluids;
λ_{SI} is the rate constant for transfer from small intestine to upper large intestine.

In the next compartment, the mean residence time is taken to be 13 h in the proximal, upper large intestine (ULI). In practice, water is absorbed from the gut content in the ULI. However, it is not necessary to model this since tritiated water is taken to be homogenously distributed across all soft tissue. Next, the mean residence time is taken to be 24 h in the distal, lower large intestine (LLI). It is noted that the LLI may be the most heavily irradiated organ if the gut uptake factor is low. This will particularly be the case for materials emitting relatively non-penetrating radiation with a short physical half-life, i.e. $\beta-$ radiation.

2.4. Verification of dosimetric data

The effective doses calculated using MIRDOSE 3.1 and OLINDA/EXM 1.0 in this work were compared to those published by the Administration of Radioactive Substances Advisory Committee (ARSAC) in 2006 (ARSAC, 2006). ARSAC is an advisory board in United Kingdom providing widely adopted notes and guidance regarding good clinical practice in nuclear medicine. The effective dose per unit of administered activity (mSv MBq-1) for orally ingested ^{111}In and ^{99m}Tc non-absorbable compounds used for GI transit studies were obtained from the ARSAC publication and compared to those calculated in this study.

3. Results

The specific radiation dose including H_T per unit of activity for each target organ (mSv MBq^{-1}) and E per unit of administered activity (mSv MBq^{-1}) estimated using the OLINDA/EXM 1.0 software are tabulated in Table 2.

The E per unit of administered activity provided by the ARSAC for oral administration of ^{111}In and ^{99m}Tc non-absorbable compounds were used to verify the doses calculated using MIRDOSE 3.1 and OLINDA/EXM in this study (Table 3). There was good agreement for the results obtained using the two methods. In general, the calculated doses for ^{111}In and ^{99m}Tc formulations were slightly higher than the ARSAC quoted data. There were no data available for ^{153}Sm formulations in the ARSAC publication.

4. Discussion

The estimation of internal radiation dose can be complicated because the radiation cannot be measured accurately or directly and the kinetics of administered radionuclides in the body vary individually. The regional amount of radionuclide uptake in the body depends on several factors, including the amount of the intake, the solubility in body fluids (which in turn depends on the particular chemical form of the radiopharmaceutical), route of administration either via inhalation, ingestion or absorption through the skin, and the physical and biological clearance of the radionuclide from the body. Even with imaging it is difficult to assess dose in vivo on an individual patient basis. Therefore data from the standard phantoms, animal models and human imaging-based population biodistribution are used.

The purpose of comparing the effective dose with the ARSAC data was to verify the appropriate use of the kinetic model and S-values applied in this study. There are little published data available for ^{153}Sm and no values quoted in the ARSAC guidance notes because it is not commonly used in diagnostic nuclear medicine. In general, the results obtained from this study were similar to those provided by ARSAC for ^{111}In and ^{99m}Tc, hence the GI tract model and kinetic data used in this study were considered valid. In comparison, the effective dose calculated using MIRDOSE 3.1 was the highest among all, followed by OLINDA/EXM 1.0 and ARSAC. However, ARSAC does not specify the subject as female or male, hence the doses for different genders could not be compared.

In general, the effective dose received by a female adult is higher than that of a male adult by approximately 7–15%. The additional absorbed dose is contributed from the radiosensitive target organ in female breasts. Among three different radionuclides labeled with non-absorbable compounds (ion-exchange resin) used for GI transit imaging, ^{153}Sm gives highest E per unit of administered activity, followed by ^{111}In and ^{99m}Tc. The excessive dose in ^{153}Sm is mainly due to the several $\beta-$ emissions in its decay scheme. As a general rule, α and $\beta-$ radiation constitute higher internal hazards compared to photons (gamma and X-rays) because of their directly ionizing properties. Although the $\beta-$ emissions from the ^{153}Sm are useful for targeted therapy, it serves no purpose in the context of imaging.

The diagnostic reference level (DRL) recommended by ARSAC for orally ingested ^{111}In non-absorbable compounds is 12 MBq (ARSAC, 2006), and this results in an estimated E of 5 and 4 mSv to the female and male patients, respectively. In comparison, the same administered activity using ^{153}Sm results in an estimated E of approximately 13 mSv

Table 2
Comparison of equivalent dose and effective dose per unit of administered activity (mSv MBq^{-1}) for ^{153}Sm, ^{111}In and ^{99m}Tc for (A) female adult and (B) male adult.

(A) Female adult

Target organ	Equivalent dose per unit of activity (mSv MBq^{-1}) – female adult								
	Beta			Photon (gamma and X-ray)			Total		
	^{153}Sm	^{111}In	^{99m}Tc	^{153}Sm	^{111}In	^{99m}Tc	^{153}Sm	^{111}In	^{99m}Tc
Adrenals	0.00E+00	0.00E+00	0.00E+00	3.52E−03	2.91E−02	3.64E−03	3.52E−03	2.91E−02	3.64E−03
Brain	0.00E+00	0.00E+00	0.00E+00	1.87E−06	4.97E−05	4.05E−06	1.87E−06	4.97E−05	4.05E−06
Breasts	0.00E+00	0.00E+00	0.00E+00	3.71E−04	3.92E−03	4.92E−04	3.71E−04	3.92E−03	4.92E−04
Gallbladder wall	0.00E+00	0.00E+00	0.00E+00	3.05E−02	1.61E−01	1.78E−02	3.05E−02	1.61E−01	1.78E−02
LLI wall	7.87E+00	1.11E+00	5.02E−02	1.89E−01	1.05E+00	3.63E−02	8.06E+00	2.17E+00	8.65E−02
Small intestine	7.66E−01	9.43E−02	2.84E−02	8.97E−02	4.52E−01	4.13E−02	8.55E−01	5.47E−01	6.97E−02
Stomach wall	3.30E−01	4.00E−02	1.69E−02	2.81E−02	1.47E−01	2.33E−02	3.59E−01	1.87E−01	4.02E−02
ULI wall	3.72E+00	4.82E−01	6.59E−02	1.39E−01	7.06E−01	6.35E−02	3.86E+00	1.19E+00	1.29E−01
Heart wall	0.00E+00	0.00E+00	0.00E+00	1.48E−03	1.19E−02	1.83E−03	1.48E−03	1.19E−02	1.83E−03
Kidneys	0.00E+00	0.00E+00	0.00E+00	8.75E−03	5.95E−02	6.83E−03	8.75E−03	5.95E−02	6.83E−03
Liver	0.00E+00	0.00E+00	0.00E+00	6.56E−03	4.20E−02	4.99E−03	6.56E−03	4.20E−02	4.99E−03
Lungs	0.00E+00	0.00E+00	0.00E+00	9.64E−04	7.94E−03	1.11E−03	9.64E−04	7.94E−03	1.11E−03
Muscle	0.00E+00	0.00E+00	0.00E+00	8.43E−03	5.02E−02	4.02E−03	8.43E−03	5.02E−02	4.02E−03
Ovaries	0.00E+00	0.00E+00	0.00E+00	9.31E−02	4.91E−01	3.06E−02	9.31E−02	4.91E−01	3.06E−02
Pancreas	0.00E+00	0.00E+00	0.00E+00	1.05E−02	6.28E−02	9.65E−03	1.05E−02	6.28E−02	9.65E−03
Red marrow	0.00E+00	0.00E+00	0.00E+00	1.17E−02	7.67E−02	5.57E−03	1.17E−02	7.67E−02	5.57E−03
Osteogenic cells	0.00E+00	0.00E+00	0.00E+00	1.58E−02	5.31E−02	5.18E−03	1.58E−02	5.31E−02	5.18E−03
Skin	0.00E+00	0.00E+00	0.00E+00	1.97E−03	1.49E−02	1.15E−03	1.97E−03	1.49E−02	1.15E−03
Spleen	0.00E+00	0.00E+00	0.00E+00	6.80E−03	4.35E−02	6.08E−03	6.80E−03	4.35E−02	6.08E−03
Thymus	0.00E+00	0.00E+00	0.00E+00	2.32E−04	2.91E−03	3.44E−04	2.32E−04	2.91E−03	3.44E−04
Thyroid	0.00E+00	0.00E+00	0.00E+00	3.06E−05	5.96E−04	5.72E−05	3.06E−05	5.96E−04	5.72E−05
Urinary bladder wall	0.00E+00	0.00E+00	0.00E+00	2.41E−02	1.36E−01	8.64E−03	2.41E−02	1.36E−01	8.64E−03
Uterus	0.00E+00	0.00E+00	0.00E+00	3.96E−02	2.19E−01	1.93E−02	3.96E−02	2.19E−01	1.93E−02
Total body	4.42E−02	5.92E−03	7.13E−04	1.00E−02	5.54E−02	4.54E−03	5.42E−02	6.13E−02	5.25E−03
Effective dose per unit of administered activity (mSv MBq^{-1})							**1.06E+00**	**4.11E−01**	**2.64E−02**

(B) Male adult

Target organ	Equivalent dose per unit of activity (mSv MBq^{-1}) – male adult								
	Beta			Photon (Gamma and X-ray)			Total		
	^{153}Sm	^{111}In	^{99m}Tc	^{153}Sm	^{111}In	^{99m}Tc	^{153}Sm	^{111}In	^{99m}Tc
Adrenals	0.00E+00	0.00E+00	0.00E+00	2.59E−03	2.11E−02	2.77E−03	2.59E−03	2.11E−02	2.77E−03
Brain	0.00E+00	0.00E+00	0.00E+00	7.79E−07	2.87E−05	2.35E−06	7.79E−07	2.87E−05	2.35E−06
Breasts	0.00E+00	0.00E+00	0.00E+00	2.32E−04	2.79E−03	3.55E−04	2.32E−04	2.79E−03	3.55E−04
Gallbladder wall	0.00E+00	0.00E+00	0.00E+00	2.21E−02	1.21E−01	1.39E−02	2.21E−02	1.21E−01	1.39E−02
LLI wall	7.43E+00	1.05E+00	4.74E−02	1.56E−01	8.70E−01	2.97E−02	7.58E+00	1.92E+00	7.71E−02
Small intestine	6.79E−01	8.36E−02	2.51E−02	6.82E−02	3.53E−01	3.12E−02	7.47E−01	4.36E−01	5.64E−02
Stomach wall	2.92E−01	3.54E−02	1.49E−02	2.14E−02	1.13E−01	1.85E−02	3.14E−01	1.48E−01	3.34E−02
ULI wall	3.37E+00	4.37E−01	5.96E−02	1.11E−01	5.71E−01	5.12E−02	3.48E+00	1.01E+00	1.11E−01
Heart wall	0.00E+00	0.00E+00	0.00E+00	9.51E−04	8.41E−03	1.30E−03	9.51E−04	8.41E−03	1.30E−03
Kidneys	0.00E+00	0.00E+00	0.00E+00	6.84E−03	4.90E−02	5.60E−03	6.84E−03	4.90E−02	5.60E−03
Liver	0.00E+00	0.00E+00	0.00E+00	4.79E−03	3.15E−02	3.75E−03	4.79E−03	3.15E−02	3.75E−03
Lungs	0.00E+00	0.00E+00	0.00E+00	5.60E−04	4.96E−03	7.03E−04	5.60E−04	4.96E−03	7.03E−04
Muscle	0.00E+00	0.00E+00	0.00E+00	6.68E−03	4.04E−02	3.23E−03	6.68E−03	4.04E−02	3.23E−03
Ovaries	0.00E+00	0.00E+00	0.00E+00	7.37E−02	3.67E−01	2.43E−02	7.37E−02	3.67E−01	2.43E−02
Pancreas	0.00E+00	0.00E+00	0.00E+00	7.56E−03	4.62E−02	7.39E−03	7.56E−03	4.62E−02	7.39E−03
Red marrow	0.00E+00	0.00E+00	0.00E+00	9.03E−03	6.26E−02	4.60E−03	9.03E−03	6.26E−02	4.60E−03
Osteogenic cells	0.00E+00	0.00E+00	0.00E+00	1.23E−02	4.25E−02	4.13E−03	1.23E−02	4.25E−02	4.13E−03
Skin	0.00E+00	0.00E+00	0.00E+00	1.56E−03	1.22E−02	9.35E−04	1.56E−03	1.22E−02	9.35E−04
Spleen	0.00E+00	0.00E+00	0.00E+00	5.27E−03	3.48E−02	4.99E−03	5.27E−03	3.48E−02	4.99E−03
Testes	0.00E+00	0.00E+00	0.00E+00	3.71E−03	2.93E−02	1.25E−03	3.71E−03	2.93E−02	1.25E−03
Thymus	0.00E+00	0.00E+00	0.00E+00	1.37E−04	2.06E−03	2.33E−04	1.37E−04	2.06E−03	2.33E−04
Thyroid	0.00E+00	0.00E+00	0.00E+00	1.24E−05	2.88E−04	2.30E−05	1.24E−05	2.88E−04	2.30E−05
Urinary bladder wall	0.00E+00	0.00E+00	0.00E+00	1.82E−02	1.13E−01	6.58E−03	1.82E−02	1.13E−01	6.58E−03
Uterus	0.00E+00	0.00E+00	0.00E+00	2.88E−02	1.67E−01	1.50E−02	2.88E−02	1.67E−01	1.50E−02
Total body	3.38E−02	4.53E−03	5.48E−04	8.00E−03	4.50E−02	3.70E−03	4.18E−02	4.95E−02	4.25E−03
Effective dose per unit of administered activity (mSv MBq^{-1})							**9.86E−01**	**3.46E−01**	**2.23E−02**

(female) and 12 mSv (male). Although ^{99m}Tc produces much lower radiation doses compared to the other aforementioned two, this radionuclide has a short physical half-life of 6 h, and therefore is unsuitable to be used for whole GI transit investigations over several days. Although the radiation dose arising from ^{153}Sm is about two and a half-times higher than that of ^{111}In, it is still comparable to the conventional radiological technique, where a series of abdominal X-ray radiographs are taken at certain time intervals following ingestion of multiple radiopaque markers. That method exposes patients to high radiation doses especially when several radiographs

Table 3
Comparison of effective dose per unit of administered activity (mSv MBq^{-1}) calculated using MIRDOSE 3.1 and OLINDA/EXM 1.0 with the dose recommended by ARSAC (2006).

Radionuclide	Effective dose per unit of administered activity (mSv MBq^{-1})				
	ARSAC	MIRDOSE 3.1		OLINDA/EXM 1.0	
		Female	Male	Female	Male
^{153}Sm	N/A	1.090	1.050	1.060	0.986
^{111}In	0.330	0.451	0.372	0.411	0.346
^{99m}Tc	0.023	0.029	0.024	0.026	0.022

N/A not available.

are taken to follow through the transit of the radiopaque markers. For example, an upper GI tract X-ray results in about 2 mSv per radiograph and a lower GI tract X-ray gives around 4–5 mSv per radiograph (Radiological Society of North America, 2007). The total investigational radiation dose varies with the number of X-ray exposures.

Recent work has shown that other radiolanthanides, eg. Lutetium-177 (^{177}Lu) may have a potential role in diagnostic as well as therapeutic nuclear medicine (Fitschen et al., 2011; Hu et al., 2002). The radionuclide, ^{177}Lu has a longer physical half-life of 6.73 days, potentially improving the shelf-life of the activated capsules for oral administration and would be suitable for the measurement of long transit times in extreme constipation. However, further work needs to be carried out to study the binding efficiency of ^{177}Lu with non-absorbable materials such as the resin formulation and to compare its radiation dosimetry with other available radionuclides.

5. Conclusion

This study has shown that the MIRDOSE 3.1 and OLINDA/EXM 1.0 software using ICRP 30 GI tract model provided good agreement with the ARSAC published values for radiation doses resulting from the oral administration of ^{99m}Tc and ^{111}In for whole GI transit studies. Therefore, the target organ equivalent dose and effective dose from orally administrated ^{153}Sm-labeled resin formulations can be regarded as reliable estimations using these software applications and the ICRP 30 GI tract model.

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