Original Article, Radio iodine Therapy and Covid-19.

Influence of COVID 19 Pandemic on Shifting High Dose I-131 Therapy to Home Isolation Practice.

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ABSTRACT:

COVID-19 pandemic forced medical facilities to postpone many elective services, including hospitalization for radioactive iodine (I131) therapy. This has negative impact on patients in need of this therapy in many countries, including Kingdom of Saudi Arabia (KSA), as they mandate hospital admission in special isolation room for few days to receive high dose I31 therapy. In other countries, this therapy is not significantly affected as high dose I-131 therapy on outpatient basis with home isolation (HDITO) is a well-established safe and effective therapeutic policy. Aim: To assess opinion of health care providers concerned with I131 therapy in KSA about HDITO and to verify acceptance to apply HDITO during current pandemic.

Material and Methods: questionnaire about HDITO was electronically dispensed to health care providers in KSA and results were

collected within four weeks to be statistically analysed. Results: Out of 101 respondents, about two thirds confirmed significant delay in giving high dose I-131 therapy due to COVID19. Half respondents agreed to apply HDITO, 85% agreement was reported for frequently involved in I-131 therapy. Avoiding treatment delay with unfavourable consequences represents the foremost etiological factor for agreement to apply the policy of giving HDITO, followed by avoiding overwhelming of health care system and saving patients from catching viral infection during the current pandemic. Respondent's agreement for application of the policy of HDITO was conditioned with presence of separate bedroom and bathroom for the patient, strict application of radiation safety instructions and proper waste disposal.

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Respondents favour the use of a communication method with the patient and his/her family as hot line for answering any question about radiation protection issues raised at any time during post therapy period. Around 63% of respondents agreed about conducting a national multi-centric clinical study, providing approval from all related governmental radiation safety authorities in KSA, to ensure the safety and efficacy of HDITO. 50% Are so willing to participate in this study, this figure increases to 85% for

those who are more frequently involved in I-131 therapy. CONCLUSION: healthcare professionals in KSA agreed to apply the policy of HDITO that appears to be good alternative to routine hospital admission during COVID19 pandemic. This study encourages performing a multi-centric research in KSA about HDITO, on approval from higher radiation safety authorities, to confirm its safety and efficacy to be applied in the future during any other pandemic.

Key Words: COVID 19 & High Dose I-131 Therapy & Home Isolation Practice.

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INTRODUCTION:

COVID-19 pandemic leads to several changes in provision of healthcare services, being forced to postpone elective services in different departments, maintaining only emergency and priority procedures (1,2). Nuclear medicine departments, during the current pandemic, try to compromise between providing essential services on one hand and minimizing the risk of viral transmission on the other hand. This will help to follow the plan of proper overcoming the challenges in the current situation (3).

High dose I-131 therapy (HDIT) to patients with thyroid cancer is one of the most important services in nuclear medicine departments. In many countries, including countries in the Middle East, it is mandatory to provide this service on inpatient basis for radiation safety issues. Yet, in the current situation, the process of hospital admission represents an obstacle in giving HDIT. Many centers ceased this service considering that I-131 therapy is not urgent and can be postponed for few months.

However, this delay may have unfavorable consequences, likely in the form of appearance of local recurrence, development of distant metastases or progression of the already present metastases ^(1,4).

In other countries, as in North America, high dose I-131 therapy is given on outpatient basis with home isolation (HDITO) without negative consequences on radiation safety neither for patient contacts nor for the environment ^(5,6).

Many articles published in the last two decades confirmed successful safe application of this policy ^(7,8). The latter appears to be a good solution during COVID-19 pandemic in countries where hospital admission is mandatory for providing HDIT.

It has the advantages of minimizing the risk of transmission of viral infection to patients receiving I-131 therapy and increasing community awareness about radiation protection instructions with more favorable psychological and economic impact to patients and families.

Aim of the work: To assess opinion of healthcare providers concerned with I-131 therapy in Kingdom of Saudi Arabia (KSA) about their agreement, requirements, obstacles and benefits of giving HDITO, as an alternative to current policy mandating

hospital admission for few days, during COVID-19 pandemic. Also, to evaluate their willingness to share in performing research study for insurance of safe application of this therapeutic policy to be employed routinely in the future or during any other coming pandemic.

MATERIALS AND METHODS:

This study is done through electronically dispensing a questionnaire to medical staff concerned with I-131 therapy in KSA. This questionnaire is about the degree of acceptance and agreement of the staff to apply the policy of giving HDITO during current pandemic with questions about requirements and instructions needed as well as obstacles and worries to be overcome for insurance of safe and successful application of this policy in KSA.

Also, the questionnaire includes questions about previous experience in application of this policy and willingness of the medical staff to participate in a national study concerned with providing this policy to special group of patients, providing presence of an agreement from radiation safety authorities in KSA. This questionnaire is collected within four weeks from dispensing and subjected to statistical analysis.

Statistical methods: Data were analysed on Statistical Package for Social Sciences (SPSS) from IBM, version 21. Numerical data were presented as mean and standard deviation if were normally distributed and categorical data were presented as percentages. Because many Likert scale questions were present in this questionnaire, there was frequent use of median and quartiles. When Likert scale answers from multiple subsections of the same question were compared, Freidman test was used.

P value <0.05 was considered statistically significant. The mean rank of Likert responses was presented to clarify the direction of variation in Likert scale answers because significant differences might exist in spite of the equality of median and quartiles.

RESULTS:

A total of 101 individuals responded to the questionnaire.

Table (1): summarizes the characteristics of questionnaire respondents.

Table (2): summarizes responses about the

availability of I-131 therapy rooms and general knowledge and opinion about outpatient high dose I-131 therapy.

Table (3): summaries the opinions of respondents regarding HDITO. Around half of respondents agree on HDITO to patients fulfilling certain criteria during COVID 19 pandemic. This figure increases to 85% for those more frequently involved in I-131 therapy.

Table (4): shows the relative importance or radiation safety criteria and precautions from the opinion of the survey respondents. All criteria were voted for by the majority of respondents but significantly higher ranks of votes went to "radiation safety instructions to be followed by all family members, and others including family helpers, such as house workers and drivers" and "The presence of a separate room and a separate bathroom for the patient in the post therapy period" (p<0.001by Friedman test). Other precautions mentioned were bracelet application and inclusion of other governmental bodies to ensure waste disposal in the proper way that does not cause environmental harm with iodine waste.

 Table (1): Characteristics of questionnaire respondents.

Characteristic	Number	Percentage						
Professional category								
Nuclear Medicine physician/radiologist	34	33.7						
Endocrinologist/endocrine surgeon	9	8.9						
Medical physicist	23	22.8						
Nuclear medicine technologist	25	24.8						
Other	10	9.9						
Professional	experience							
Less than 10 years	52	51.5						
More than 10 years	49	48.5						
Extent of involvement	ent in ¹³¹ I therapy	,						
Always	35	34.7						
Usually	21	20.8						
Sometimes	18	17.8						
Rarely	14	13.9						
Never	10	9.9						
No answer	3	3.0						

Table (2): Availability of I-131 therapy rooms and general knowledge and opinion about outpatient therapy.

Response	Number	Percentage						
Isolation room availability								
No	55	54.5						
Yes	46	55.5						
During the current COVID 19 pandemic, have you faced delay in HDIT								
Yes, for whole respondents	55	54.5						
Yes, for those usually and always involved in	37	80.4						
therapy								
Do you know that HDITO has been routinely applicable in some countries without violating radiation safety?								
Yes	56	55.4						
Do you have any experience in application of HDTO?								
Yes	22	21.8						

Table (3): The opinions of respondents regarding HDITO.

Question	Response [n (%)] Med								
	Strongly agree	Agree	Neutral	Disagree	Strongl disagre	.5	(quartiles) [Mean rank]		
Agreement on giving	26(25.7)	24(23.8)	45(44.6)	3(3.0)	3(3.0)	(-5)			
HDITO	Valı	Values for those usually and always involved in ¹³¹ I therapy							
	19(33.9)	14(25.0)	21(37.5)	1(1.8)	1(1.8)	_	7.0]		
		Values for those less involved in ¹³¹ I therapy							
	7(15.6)	10(22.2)	24(53.3)	2(4.4)	`	4.4)	[43.7]		
P value for comparing t	hose freque	ently involv	ed in thera	py with tho	se less in	volved	0.016		
Ration	al for the a	nswer of th	e above ste	m question			P value		
Radiation safety has	13	31	52	4	1	3			
not been violated on applying HDITO	(12.9)	(30.7)	(51.5)	(4.0)	(1.0)	(3-4) [2.5]			
To save hospital beds	27	32	36	4	2	3			
and medical staff	(26.7)	(31.7)	(35.6)	(4.0)	(2.0)	(3-5)			
services confined to COVID19						[3.04]	< 0.00		
Avoiding treatment	37	24	39	1	0	4	1		
delay with its	(36.6)	(23.8)	(38.6)	(1.0)		(3-5)			
unfavourable consequences						[3.34]			
Save patients from	32	28	39	1	1	4			
catching COVID19	(31.7)	(27.7)	(38.6)	(1.0)	(1.0)	(3-5)			
infection	22	20	40	7	0	[3.23]			
To reduce economic burden to families or	23 (22.8)	29 (28.7)	42 (41.6)	7 (6.9)	0	4 $(3-4)$			
government	(22.0)	(20.7)	(11.0)	(0.7)		[2.89]			
Agreement about the level of commitment to COVID19 quarantine instructions is a good indicator									
				uctions duri	ng HDIT				
Respondents	20	24	47	8	2	3			
agreement	(19.8)	(23.8)	(46.5)	(7.9)	(2.0)	(3 - 4)			

Table (4): The opinions of respondents regarding the importance of criteria that influence safety of out-patient I-131 therapy.

Criterion	Respo	nse rega	Median	P value			
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	(quartiles) [Mean rank]	
No viral infection during COVID19	35 (34.7)	27 (26.7)	36 (35.6)	3 (3.0)	0	4 (3 – 5) [3.58]	
Proper explanation of full RSI* to patient and all household contacts	46 (45.5)	17 (16.8)	36 (35.6)	1 (1.0)	1 (1.0)	4 (3 – 5) [3.97]	
Answering all questions of the patient and household contacts	47 (46.5)	16 (15.8)	36 (35.6)	1 (1.0)	1 (1.0)	4 (3 – 5) [4.03]	
Presence of a separate bedroom & bathroom for the patient	50 (49.5)	16 (15.8)	34 (33.7)	0	1 (1.0)	4 (3 – 5) [4.21]	
No pregnant ladies or children in the house in the first 3 days post	45 (44.6)	15 (14.9)	36 (35.6)	4 (4.0)	1 (1.0)	4 (3-5) [3.94]	
RSI should be followed by all household contacts	51 (50.5)	15 (14.9)	33 (32.7)	1 (1.0)	1 (1.0)	5 (3 – 5) [4.21]	<0.001
Willingness of the patient and household contacts to strictly apply RSI	45 (44.6)	21 (20.8)	34 (33.7)	1 (1.0)	0	4 (3 – 5) [4.05]	

^{*}RSI:Radiation safety instructions

Table (5): shows the opinions of respondents regarding the importance of recommendations governing out-patient I-131 therapy. "Making available a hotline or tele application for patients and household contacts to answer their questions about radiation protection or any situation that might happen during the post therapy period" had the highest vote rank statistically (p = 0.001).

Table (6): summarizes the opinions of respondents regarding the expected risks associated with HDITO. Generally speaking all listed risks had agreement votes from less than a third of respondents and none of the suggested risks showed a significant statistical marker among other listed risks (p = 0.158 by Friedman test).

Around 63% of respondents agreed in conducting a multi-centric study about HDITO and around 50% indicated their willingness to participate in this study.

Among those frequently involved in I-131

therapy, 85% were willing to participate in conducting this national study, on approval from higher authorities concerned with radiation safety issues in KSA.

Table (5): The opinions of respondents regarding the importance of recommendations governing HDITO.

Recommendation	Resp	onse rega	Median (quartiles)	P value			
	SR*	R*	N *	DR*	SA*	[Mean rank]	
The application of personal dosimetric device for all household contacts	20 (19.8)	21 (20.8)	47 (46.5)	13 (12.9)	0	3 (3-4) [1.82]	
Available hotline or tele application for patients and household contacts	33 (32.7)	24 (23.8)	43 (42.6)	1 (1.0)	1 (1.0)	4 (3-5) [2.13]	0.001
Visit by the RSO* to discharge the patient from the home isolation and radiation measurements	31 (30.7)	20 (19.8)	43 (42.6)	6 (5.9)	1 (1.0)	4 (3 – 5) [2.05]	

^{*}SR: strongly recommend-R: recommend-N: neutral -DR: do not recommend-SA: strongly against **RSO: Radiation safety officer

Table (6): The opinions of respondents regarding the important risks associated with out-patient I-131 therapy.

Risk	Respo	nse rega	Median	P value			
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	(quartiles) [Mean rank]	
The patients will not stick strictly to RSI*	17 (16.8)	21 (20.8)	47 (46.5)	14 (13.7)	2 (2.0)	3 (3 – 4) [2.6]	
Household contacts will be exposed to high dose radiation.	9 (8.9)	24 (23.8)	41 (40.6)	16 (15.8)	1 (1.0)	3 (3 – 4) [2.37]	
Customs and traditions.	12 (11.9)	24 (23.8)	50 (49.5)	13 (12.9)	2 (2.0)	3 (3 – 4) [2.58]	0.158
Difficulty to follow those patients in their houses	12 (11.9)	23 (22.8)	48 (47.5)	13 (12.9)	5 (5.0)	3 (3 – 4) [2.45]	

DISCUSSION:

The WHO characterized the novel coronavirus COVID-19, first isolated in Wuhan, China, as a pandemic on March 11^{th} 2020. Since that time healthcare resources should be spared to the maximum extent possible, even a small amount of healthcare resources spent for a non-urgent treatment will be in direct conflict with this greater social problem. Moreover, some healthcare authorities ordered all their registered medical staff of different specialties to assist in isolation hospitals wherever needed. This automatically has a direct impact on scheduled therapies (9). Hospitalization for few days in a special isolation room is the policy of HDIT in most European countries as well as in Middle East region including KSA. Yet, HDITO is a well-established applied therapeutic policy in many countries since more than two decades with no evidence of violation of radiation safety, as in North America and in some countries of South East Asia (7, 8).

In KSA thyroid cancer represents a healthcare burden as it represents 8.8% of all malignancies in Saudi Arabia. It is the second most common cancer among Saudi females. More than half of respondents indicated that isolation rooms for HDIT are not available in

their hospitals.

Actually there is shortage of isolation rooms especially in rural areas, even available isolation rooms are not equally distributed in different areas of KSA, increasing obstacles facing patients in need of HDIT with resultant some delay. The current COVID-19 pandemic aggravates this delay with more patients in need of this form of therapy in the pipeline, increasing their number in the waiting list.

All these facts strongly urge us to look for a solution to avoid treatment delay with its unfavorable consequences. In the meantime, saving patients from getting current viral infection and avoiding overwhelming of healthcare facilities in current situation are other important main goals that have to be strongly kept in mind.

During COVID-19 pandemic, around 50% of respondents stated evident delay in giving HDIT. This figure of treatment delay jumps to 66% for respondents who are more involved in I-131 therapy. These figures confirm the effect of COVID-19 in aggravating the problem that appears to become more complicated in the months of the pandemic and even after the pandemic, increasing demands of HDIT for more patients.

These data are concordant with what was reported by *Freudenberg*, et al. 2020 ⁽¹⁰⁾, who stated that I-131 therapy was reduced by 41.8% in Europe after the pandemic has reached its first peak. It was reported that I-131 is often used for post-operative thyroid remnant ablation. Delays of six months or even longer do not appear to negatively affect the course of thyroid cancer in those patients. Therefore, short delays expected from waiting until COVID-19 pandemic is over are unlikely to lower the effectiveness of the I-131 therapy (11). Tsang et al 2019, raised the issue of I131 delay to avoid patients from getting viral infection, stating that patients awaiting radioiodine therapy may find that their treatment was postponed during the pandemic for safety reasons. They reported that though the treatment itself does not increase the risk of infection, the fears come from the fact that subsequent radiation protection issues post I-131 therapy would seriously complicate the care of any patient who subsequently became unwell with COVID-19 (11, 12).

In the absence of a dead time for the end of this pandemic, mounting up to more than nine months nowadays, with expected more prolongation together with the appearance of a second and possible third waves may prolong postponing elective therapeutic procedure with unpredicted return to full hospital services including HDIT.

Moreover, we have to take into consideration I-131 treatment is more urgent for that who have distant metastases, patients particularly if growth of the metastases has been observed, urging for giving I-131 without any delay (11). The challenge for the nuclear medicine physician lies weighing up the risk of a delay in treatment of thyroid malignancy against the patient's risk to be affected by COVID-19, especially in higher risk groups as those with progressive distant metastases and/ or those with associated diabetes or other comorbid disease. As a matter of fact HDIT in the proper time must be guaranteed in selective cases knowing that this type of cancer is not associated with higher incidence of COVID-19 infection as reported for other malignancies. In KSA this guarantee should be for a selected group of patients on a broader base due to the situation of the disease itself as well as the shortage of infrastructure and personnel required for this form of therapy.

The current study is the first cross sectional study in KSA about influence of COVID-19 pandemic in changing the therapeutic policy mandating hospital admission to receive HDIT to HDITO.

Around 55% of respondents reported that they have good theoretical knowledge about the policy of HDITO. Moreover, 22% confirmed that they have an actual clinical experience with HDITO, being actively involved in this therapeutic policy during their fellowship training programs outside the kingdom.

This means that more than 75% of those involved in I131 therapy in KSA have a good background about safe application of this policy and around one third of them are ready to apply this procedure practically in a proper and safe manner.

We are sure that they are also so ready to share their practical experience with the rest of the group as well as with the new generations, raising a team capable of establishing the policy of HDITO in the kingdom and beating the aforementioned growing problem, if this policy is approved by the concerned radiation safety authorities in KSA.

Around half of the respondents agree to give HDITO to some group of patients, fulfilling certain criteria to ensure radiation safety, during the COVID -19 pandemic. This figure increases to 60% for those more commonly involved in I-131 therapy procedure, with significant difference compared to 38% for

those who are less concerned with I-131 therapy (p 0.016).

This indicates that more than half of healthcare practitioners concerned with I-131 therapy accept the idea of application of HDITO in the current pandemic.

The most significant factor encouraging them for this acceptance is to avoid treatment delay with its unfavorable consequences as local recurrence and/or development of regional or distant metastases. The progression of already present metastatic lesions is another unfavorable outcome of treatment delay. The factor of avoiding treatment delay is statistically significant compared to other important factors. The later include protection of patients from catching viral infection together with preventing overwhelming of hospitals and medical staff during the pandemic. The agreement about application of HDITO also means that there is high confidence that this policy will not have a negative impact on radiation safety particularly if radiation safety instructions are given in the proper way to patients and family members. This is due to the fact that people always show strict and proper response to instructions if related to their own family health.

This becomes clear during the pandemic where almost all different population categories show great commitment regulations government and quarantine instructions given in a proper way to avoid the spread of COVID-19 in the community. Therefore, this disease was almost under control in Saudi Arabia. This great commitment by Saudi population represents a good indicator of strict and proper adherence to radiation safety instructions by concerned patients and families on giving HDITO. This is agreed upon by around 40% of the respondents. Practically, this is in agreement with what was reported by Salman et al 2019 (13), who stated that proper giving of radiation safety instructions by professionals to all family members of patients treated with low dose I-131 (1110 MBq) on outpatient basis represents the cornerstone of strict adherence to these They instructions. reported no single overexposure in all included household will These facts contacts. urge the establishment of HDITO policy during the pandemic and thereafter in the future to become routine medical practice as in many other countries with its advantages

reducing the economic and psychological patients burden and families and established awareness of the whole protection community about radiation avoiding personnel measures or environmental radiation safety violation.

As regards essential requirements for giving HDITO, significantly higher ranks of votes go to presence of a separate bed room and a separate bathroom for the patient in the post therapy period. This is followed by mandating strict adherence to radiation safety instructions by all family members and others including family helpers.

Most respondents raise the idea of making available hotline or tele-application for patients and household contacts to answer their questions about radiation protection or any situation that might happen during the post therapy period. This recommendation most likely was selected because it is easy to apply and will significantly improve the communication with the patients and their families. It is actually present in many forms as chatting and videos for multiple purposes, employed successfully during the COVID-19 pandemic including patient assessments and psychological support.

Other recommendations such the application of thermo luminescent dosimeters (TLDs) or digital wireless personal radiation dose-meter to all household contacts or making home visit few days post therapy by the radiation safety officers (RSO) are more expensive and need more personnel and were strongly recommended bv the not respondents.

These two modalities of application of a home visit by radiation safety officer together with five days application of TLD to all household contacts of patients treated with low dose I-131 therapy were used in Salman et al study 2018 (14). They reported evidently low exposure rate readings in the post therapy period to all household contacts, almost less than 20% of the internationally recommended annual exposure rate. Also, the RSO visit on fifth day post therapy confirmed absence of areas of significantly high radiation exposure readings during home inspection and radiation activity measurement. This was attributed to strict adherence of all household contacts to the properly given radiation protection instructions by trained personnel which is one of the most important requirement by the respondents in the current study.

The opinions of the respondents regarding the obstacles and difficulties associated with

outpatient I-131 therapy had agreement votes from less than a third of respondents and none of the suggested obstacles and difficulties was statistically significant compared to others (P=0.158).

This result indicates that most of the respondents believe that they can be mitigated and controlled and they will not prevent the implementation of HDITO in the Kingdom.

Around 63% of respondents agreed about conducting a national multi-centric clinical study, providing approval from all related governmental radiation safety authorities in KSA, to ensure the safety and efficacy of HDITO. 50% agreed to participate in this study with presence of adequate personnel and infrastructures to share in performing the study.

This figure increases to 85% for those who are more frequently involved in I-131 therapy, denoting that they are more aware of the problem on one hand and they are more convinced by both safety and efficacy of HDITO on the other hand. The above data together with the fact that Saudi population are properly committed to governmental measures during COVID-19 pandemic guarantee to a great extent that they are going adhere strictly to radiation safety instructions.

Actually, the current pandemic represents an excellent challenge to healthcare practitioners involved in I-131 therapy in the Kingdom to start this research project. Besides, this research will pave the way for other countries in the region to re-evaluate their HDIT policy, urging them to start similar research studies to assure safe and efficient application of HDITO.

CONCLUSIONS:

In view of treatment delay in giving HDIT due to COVID-19 pandemic, many healthcare professionals involved in I-131 therapy in KSA agreed to apply the policy of HDITO that appears to be a good alternative to routine hospital admission. This agreement is conditioned with many requirements that can

be achieved and some obstacles and worries that can be overcame. Main requirements include presence of a separate bathroom and bed room for the patient, good communication method in post therapy period together with properly giving radiation safety instructions. Proper compliance to quarantine instructions during the pandemic seems to be a good indicator for proper application of radiation safety instructions during HDITO.

This study encourages performing a multicentric research project in KSA about HDITO, to confirm its safety and to gain more experience to be applied in the future whether routinely or during any other coming pandemics. This can pave the way for application of the policy of HDITO in other countries in the region.

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