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ORIGINAL PAPER

IMPACT OF COVID-19 ON HEALTH-RELATED QUALITY OF LIFE (HR-QOL) IN CANCER PATIENTS

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Abstract

Introduction. The COVID-19 pandemic caused significant psychological symptoms, especially in cancer patients who are at higher risk for infections.
The objective of the study was to assess the quality of life (QoL) and mental health in cancer patients during COVID-19 pandemic.
Material and methods. A single centre, cross sectional observational study was conducted in the Medical and Radiation Oncology Departments of a tertiary care hospital. Cancer patients who underwent radiation therapy and/or chemotherapy during COVID-19 lockdown

Résumé

Impact du COVID-19 sur la qualité de vie liée à la santé (HR-QOL) chez les patientes atteintes de cancer

Introduction. La pandémie de COVID-19 est un événement extrêmement stressant qui peut provoquer des symptômes psychologiques importants, en particulier chez les patients atteints de cancer qui présentent un risque plus élevé des infections.
L'objectif de l'étude est d'évaluer la qualité de vie (QdV) et la santé mentale des patients atteints de cancer pendant la pandémie de COVID-19.

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period were retrospectively interviewed in person or through telephonic conversations to assess their health-related quality of life (HRQoL), depression, and anxiety status using validated questionnaires (EORTC QLQC-30, HAM-D and CAS scales, respectively).

Results. A total of 354 patients were interviewed, of whom 146 (41.2%) were male patients and 208 (58.8%) were female patients. The age range of the study participants was 18 to 83 years, with an average age of 52.7 years. Most patients had completed high school (92, 26.2%), their house hold income ranged between 2641-7886 Rs/Month (143, 40.7%) and they belonged to the "upper lower" socio-economic class (234, 66.7%). Depression and anxiety were significantly associated with HRQoL (OR: 1.22; 95%CI: 1.04-1.40;p= 0.001) and (OR: 0.53; 95 %CI: 0.08-0.98; p= 0.02).

Conclusions. The study identified that COVID-19 had no impact on the HRQoL of cancer patients who had undergone radiation therapy and/or chemotherapy during the pandemic. The depression caused by cancer and the adverse effects of the chemo and radiation therapy had significantly affected their QoL, especially their physical, functional, and mental health.

Keywords: quality of life, depression, anxiety, cancer, COVID-19 pandemic.

List of abbreviations:
CAS – coronavirus anxiety scale
COVID-19 – coronavirus disease 2019
DSM – diagnostic for statistical manual of mental disorders
EORTC QLQ-C30 – European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire
HAMD – Hamilton depression rating scale
HRQoL – health-related quality of life
MERS – Middle East respiratory syndrome
QoL – quality of life
SARS – severe acute respiratory syndrome

Materiel et méthodes. Une étude observationnelle transversale à entrée unique a été menée dans les services de médecine et de radio-oncologie d'un hôpital de soins tertiaires. Les patients atteints de cancer qui ont subi une radiothérapie et/ou une chimiothérapie pendant la période de confinement liée à la COVID-19 ont été interrogés rétrospectivement en personne ou par le biais de conversations téléphoniques pour évaluer leur qualité de vie liée à la santé (QdVLS), leur dépression et leur état d'anxiété à l'aide de questionnaires validés (échelles EORTC QLQC-30, HAM-D et CAS, respectivement).

Résultats. Un total de 354 patients ont été interrogés, dont 146 (41,2%) étaient des hommes et 208 (58,8%) étaient des femmes. La tranche d'âge des participants à l'étude était comprise entre 18 et 83 ans avec un âge moyen de 52,7 ans. La majorité des patients avaient terminé leurs études secondaires (92, 26,2%), leur revenu familial se situait entre 2641 et 7886 roupies/mois (143, 40,7%) et ils appartenaient à la classe socio-économique "supérieure inférieure" (234, 66,7%). La dépression et l'anxiété étaient significativement associées à la qualité de vie liée à la santé (OR: 1,22; IC à 95%: 1,04-1,40; p=0,001) et (OR: 0,53; IC à 95%: 0,08-0,98; p=0,02).

Conclusions. L'étude a identifié que COVID-19 n'avait aucun impact sur la qualité de vie liée à la santé des patients atteints de cancer qui avaient subi une radiothérapie et/ou une chimiothérapie pendant la pandémie. La dépression causée par le cancer et les effets indésirables de la chimiothérapie et de la radiothérapie ont considérablement affecté leur qualité de vie, en particulier leur santé physique, fonctionnelle et mentale.

Mots-clés: qualité de vie, dépression, anxiété, cancer, pandémie de COVID-19.

Introduction

The coronavirus outbreak has expanded to 199 nations and territories throughout the world (including the cruise liner Diamond Princess in Yokohama, Japan), affecting approximately 556,141 persons who have tested positive for the virus. The overall death reached to 252337[1]. The pandemic spread rapidly worldwide, with a higher 2-3% fatality rate compared to severe acute respiratory syndrome (SARS) in 2003 and Middle East respiratory syndrome (MERS) in 2012[2]. According to diagnostic for statistical manual of mental disorders (DSM) criteria, the depression rates in cancer patients are up to three times higher than in the general population, ranging between 2.0–43.5%, with palliative care wards reporting rates as high as 49.0%[3].

In general, the cancer progression has been connected to greater depression levels. Depression is significantly more prevalent in patients experiencing high levels of pain compared to those with low pain levels[4]. Several clinical guidelines for COVID-19 prevention and management were developed to help cancer patients avoid serious health implications[5]. Cancer treatment was influenced by COVID-19 pandemic, and it has exacerbated patients' psychological anguish. Previous research examined the risk of anxiety, sadness, as well as post-traumatic stress disorder during

the epidemic,[6] which cause financial difficulties and uncertain economic situations[7]. Uncertainty in depression and quality of life (QoL) prevalence arises from different assessment methods, patient demographics, age, gender differences, and inpatient status[8,9].

The objective of the study was to investigate the QoL and mental condition in terms of anxiety and depression among cancer patients who had had radiation therapy and/or chemotherapy, during COVID –19 pandemic.

Material and methods

Study design, population, and site

It was a single centre, cross-sectional, observational study, carried out in the Medical Oncology and Radiation Oncology department, Sri Ramachandra Medical College and Research Institute, Chennai, India. The study was approved by the ethics committee of Sri Ramachandra Institute of Higher Education and Research, Chennai, India (IEC/21/JAN/89/63, date 15/03/2021). The participants were enrolled after signing the informed consent form. A total of 354 cancer patients with solid tumours of all stages, of either sex, aged ≥19 years, who visited hospital to receive chemotherapy of any cycle or radiation treatment during COVID-19 lockdown period (April 2020 to September 2020) were included. The patients referred to surgery were excluded.

Questionnaires scales used to assess the collection of demographic data, QoL, depression and anxiety

The participants demographic details were collected through employing the Modified Kuppuswamy scale[10]. The QoL among cancer patients was assessed using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). The Coronavirus Anxiety Scale (CAS) identified probable cases of dysfunctional anxiety related to the COVID-19 crisis, while the Hamilton Depression Rating Scale (HAMD), a multi-item questionnaire, was used to indicate the levels of depression[11-13]. These questionnaires were administered and responses were used to assess their mental status and health-related QoL (HRQoL).

The QLQ-C30 questionnaire includes five functional scales, three symptom scales, a global health status/QoL scale, and six individual items. Each scale's score is calculated using a specific formula, with a score generated for functional, symptom, and global health categories. Higher scores on the functional and global health scales indicate better quality of life and functioning, while a higher symptom score reflects greater health issues. First, the raw score is calculated by averaging the items for each scale. Then, a linear transformation is applied to standardize the score, resulting in a range from 0 to 100.

$$\text{Raw Score} = \text{RS} = \frac{(\text{I1} + \text{I2} + \cdots + \text{In})}{\text{n}}$$

The linear transformation should be applied to 0-100 to obtain the score S.

$$\text{FUNCTIONAL SCALES, S} = \left\{1 - \frac{\text{RS} - 1}{\text{RANGE}}\right\} \text{X100}$$

$$\text{SYMPTOMS SCALE, S} = \left\{\frac{\text{RS} - 1}{\text{RANGE}}\right\} \text{X100}$$

$$\text{GLOBAL HEATH STATUS OR QOL, S} = \left\{\frac{\text{RS} - 1}{\text{RANGE}}\right\} \text{X100}$$

The range is defined as the difference between the lowest and highest possible responses for each item. For functional and symptom scales, this range is set at 3, while for the global health status scale, it is 6. Scores were analysed following the European Organization for Research and Treatment of Cancer (EORTC) methodology and guidelines (https://qol.eortc.org/manuals/). A higher score on functional scales indicates better functioning, with scores below 33.33% considered to reflect significant impairment of QoL, and scores above 66.66% suggesting a minimal impact on QoL. Conversely, higher scores on symptom scales indicate worse functioning, with scores below 33.33% signifying a lower symptom burden, and scores above 66.66% representing a significant symptom burden due to cancer. Additionally, the study utilized the Coronavirus Anxiety Scale (CAS) and assessed depressive symptoms using the Hamilton depression rating (HAMD) scale, with cut-off scores of 7 for HAMD and 9 for CAS.

Sample size

A sample size of 354 was arrived with IBM SPSS (Version 26). The sample size of expected single proportion assuming 0.23, the relative precision 20%. The desired confidence level (1- alpha), 95%. The required sample size is 322. Assuming 10% of the study subjects will be lost for follow-up, the sample size is intended to 354.

Statistical analysis

The statistical analysis was conducted using IBM SPSS Statistics-26. Frequencies, percentages, means, standard deviations, T-tests, ANOVA, Chi-square tests, Pearson correlation, and Fisher's exact tests were calculated to determine associations between

categorical variables. Multivariable logistic regression was employed to estimate adjusted odds ratios (OR) for assessing independent risk factors associated with CAS and HAM-D using EORTC. A p-value of <0.05 was considered statistically significant.

Results

A retrospective study was done in 354 patients with cancer who attended the Oncology Department for chemotherapy and radiation therapy. Out of 354 patients, 146 (41.2%) were male patients and 208 (58.8%) were female patients. The age range of the study participants was found to be 18 to 83 years, with a mean age of 52.7±21.8 yrs. Most patients were aged between 40-70 years. The history of COVID-19 was encountered in 23 (6.5%) patients. Most patients were unemployed (113, 32.3%) (Table 1).

Table 1 Distribution of study population based on age, gender, and history of COVID-19

Variables		*Number of patients (n=354)*	
		Frequency (n)	%
Age range (years)	< 20	6	1.7
	21 – 30	14	4.0
	31 – 40	40	11.3
	41 – 50	99	28.0
	51 – 60	83	23.4
	61 – 70	81	22.9
	71 – 80	29	8.2
	>80	2	.6
Gender	Male	146	41.2
	Female	208	58.8
History of COVID-19	Yes	23	6.5
	No	329	92.9

Table 2. Socio economic status of the patients (modified Kuppuswamy scale).

Socio demographic details	*Number of patients (N=354)*	%	X^2 *p-value*
Occupation of patient			
Unemployed	113	32.2	0.185
Unskilled worker	70	19.9	
Semi-skilled worker	49	14.0	
Skilled worker	49	14.0	
Clerical-shop-owner/farm	24	6.8	
Semi-professional	26	7.4	
Professional (white collar)	20	5.7	
Education of patient			
Illiterate	40	11.4	0.214
Primary school certificate	63	17.9	
Middle school certificate	74	21.1	
High school certificate	92	26.2	
Intermediate or post high school diploma	50	14.1	
Graduate or postgraduate	20	5.7	
Professional degree	12	3.4	
Family Income (rupees/month)			
< 2640	47	13.4	0.523
2641 – 7886	143	40.7	
7887 – 13160	70	19.9	
13161 – 19758	50	14.2	
19759 – 26354	7	2.0	
26355 – 52733	31	8.8	
>52734	3	.9	
Socioeconomic class			
Lower	10	2.8	0.874
Upper Lower	234	66.7	
Lower middle	69	19.7	
Upper middle	35	10.0	
Upper	3	0.9	

The socioeconomic status of the participants was assessed using the Modified Kuppuswamy scale. Most patients belonged to the upper lower socioeconomic class, with a family income ranging between 2641-7886 Rs/Month. The most common occupations were "unemployed" and "unskilled worker". Nearly a quarter of the patients had attained a high school certificate as their highest level of education. There were no statistically significant associations between patient occupation or education level and the likelihood of participating to the study (Table 2). This study examined the relationship between a prior COVID-19 diagnosis and HRQoL among cancer patients undergoing chemotherapy and/or radiation therapy. We compared EORTC QLQ-C30 scores between patients with and without a history of COVID-19, to identify potential differences in their experiences. The analysis of the 95% confidence intervals revealed a statistically significant difference in fatigue between individuals with and without a history of COVID-19. COVID-positive individuals reported significantly higher fatigue levels compared to those without a COVID-19 history. However, both groups scored within the "Mild Symptoms" range, suggesting that while statistically significant, the difference may have a limited impact on daily life. The data also suggest a potential difference in emotional functioning, although it borders on statistical significance. Individuals with a history of COVID-19 trend towards poorer emotional functioning compared to those without. Nevertheless, both groups fall within the "moderate functioning" range, indicating a moderate level of emotional well-being. No statistically significant differences were found between the two

Table 3. Impact of COVID-19 history on QoL assessed by European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) in cancer patients.

Quality of Life Parameters	*History of COVID-19*	*Mean ± SD*	*Sig. (2-tailed)*	*Mean Difference*	*95% CI*	
					Lower	*Upper*
Nausea vomiting	No	83.64±21.54	0.93	-0.36	-9.04	8.31
	Yes	84±17.00				
Fatigue	No	50.76±15.19	0.04	6.32	0.23	12.40
	Yes	44.44±10.64				
Physical function	No	14.78±17.27	0.85	-0.69	-7.74	6.36
	Yes	15.47±17.40				
Role function	No	25.10±28.09	0.71	-2.23	-13.82	9.35
	Yes	27.33±32.23				
Emotional	No	37.02±29.53	0.10	-10.31	-22.44	1.81
	Yes	47.33±32.25				
Cognitive	No	11.03±17.40	0.66	-1.64	-8.96	5.68
	Yes	12.67±24.19				
Social function	No	16.41±24.61	0.18	-6.92	-17.02	3.18
	Yes	23.33±26.79				
Dyspnea	No	16.36±25.50	0.49	-3.64	-14.09	6.82
	Yes	20±27.22				
Insomnia	No	21.24±31.55	0.83	-1.43	-14.22	11.36
	Yes	22.67±28.41				
Appetite	No	22.56±28.50	0.64	-2.77	-14.51	8.97
	Yes	25.33±32.32				
Constipation	No	16.67±26.80	0.27	6.00	-4.79	16.79
	Yes	10.67±20.91				
Diarrhea	No	19.61±30.43	0.31	6.28	-5.97	18.53
	Yes	13.33±23.57				
Finance	No	44.92±39.06	0.35	7.58	-8.41	23.58
	Yes	37.33±41.19				
QoL	No	66.59±19.35	0.49	-2.74	-10.57	5.08
	Yes	69.33±16.62				

Table 4. Descriptive statistics of HAMD scores in cancer patients.

ANOVA QoL Vs HAMD	*Groups*	*Sum of Squares*	*df*	*Mean Square*	*F*	*Sig.*
Fatigue	B/w groups	0.67	1.00	0.67	2.324493	0.12825
	Within Groups	101.86	352.00	0.29		
	Total	102.53	353.00			
Nausea, vomiting	B/w groups	0.52	1.00	0.52	3.730323	0.054236
	Within Groups	48.63	352.00	0.14		
	Total	49.14	353.00			
Pain	B/w groups	0.00	1.00	0.00	0.001076	0.973852
	Within Groups	106.61	352.00	0.30		
	Total	106.61	353.00			
Physical function	B/w groups	1.51	1.00	1.51	8.336549	0.004126
	Within Groups	63.56	352.00	0.18		
	Total	65.06	353.00			
Role function	B/w groups	0.01	1.00	0.01	0.01749	0.894862
	Within Groups	203.22	352.00	0.58		
	Total	203.23	353.00			
Emotional	B/w groups	0.82	1.00	0.82	1.291976	0.256457
	Within Groups	222.25	352.00	0.63		
	Total	223.06	353.00			
Cognitive	B/w groups	0.16	1.00	0.16	0.74817	0.387645
	Within Groups	75.79	352.00	0.22		
	Total	75.95	353.00			
Social function	B/w groups	0.85	1.00	0.85	2.156883	0.142825
	Within Groups	139.41	352.00	0.40		
	Total	140.26	353.00			
Dyspnea	B/w groups	1.08	1.00	1.08	2.179854	0.140722
	Within Groups	175.19	352.00	0.50		
	Total	176.27	353.00			
Insomnia	B/w groups	0.46	1.00	0.46	0.703741	0.402099
	Within Groups	227.98	352.00	0.65		
	Total	228.44	353.00			
Appetite	B/w groups	0.79	1.00	0.79	1.226412	0.268862
	Within Groups	225.48	352.00	0.64		
	Total	226.26	353.00			
Constipation	B/w groups	0.72	1.00	0.72	1.467016	0.22663
	Within Groups	172.96	352.00	0.49		
	Total	173.68	353.00			
Diarrhea	B/w groups	0.26	1.00	0.26	0.414598	0.520064
	Within Groups	220.01	352.00	0.63		
	Total	220.27	353.00			
QoL	B/w groups	0.52	1.00	0.52	1.885646	0.170568
	Within Groups	96.36	352.00	0.27		
	Total	96.87	353.00			

groups in other measured areas, including pain, nausea, physical, role, cognitive, and social functioning, sleep quality, appetite, and digestion. The patients usually reported low scores on symptom scales measuring dyspnea, constipation, diarrhea, appetite, insomnia, and vomiting, as well as high scores in the pain, nausea, and vomiting domain. In contrast, patients reported moderate to good scores on functional scales measuring role functioning, physical function, cognitive and social functioning, emotion, and quality of life (Table 3).

The ANOVA results revealed a significant impact of HAMD scores on physical function. This suggests that variations in depression severity

Table 5. Correlation between CAS Score and HAMD in cancer patients.

Scores	Mean ± SD	r value	p-value
CAS Score	1.2±2.3	0.366	0.00
HAMD	9.0±5.7		

Table 6. Correlation between history of COVID-19 and depression

History of COVID –19	*HAM-D*		*Total*	*x^2 Value*	*p-value*
	Normal	*Moderate*			
Yes	161	170	331	8.16	0.017
No	5	18	23		
Total	166	188	354		

p <0.05: Statistically significant

Table 7. Association of CAS and HAMD with EORTC QLQ C30

HRQoL (EORTC QLQ C30 transformed scores)	*Odds ratio (OR)*	*95% Confidence Interval*		*t-test p-value*
		Lower Bound	*Upper Bound*	
Anxiety (CAS scores)	0.536	0.082	0.989	0.02*
Depression (HAM-D Scores)	1.224	1.041	1.406	0.001**

*: Statistically significant; **: Highly significant

significantly influenced physical functioning levels among the participants. In contrast, HAMD scores did not significantly affect other QoL domains, such as fatigue, nausea/vomiting, pain, role function, emotional well-being, cognitive function, social functioning, dyspnea, insomnia, appetite, constipation, diarrhea, and overall QoL. These findings highlight the specific and notable influence of depression on physical function within the study cohort (Table 4). To further investigate the relationship between COVID-19-related anxiety and depression, we examined the correlation between the CAS score and the HAMD score. As shown in Table 5, there was a statistically significant positive correlation between CAS scores and HAMD scores (r = 0.366, p = 0.00). This suggests that higher levels of COVID-19-related anxiety are associated with higher levels of depression in this population. The chi-square test yielded a value of 8.16 with a corresponding p-value of 0.017, indicating a statistically significant association between a history of COVID-19 and higher levels of depressive symptoms measured by the HAMD scale. This suggests that patients with a history of COVID-19 are more likely to experience moderate levels of depression compared to those without such a history (Table 6). The adjusted odds ratio analysis suggested a greater likelihood of an association between depression and poorer health-related QoL, compared to the association between anxiety and QoL. Specifically, the odds ratio of 1.224 indicates that depression had a significant, positive relationship with QoL outcomes. In contrast, the odds ratio of 0.536 for anxiety suggests a comparatively lower, yet statistically significant, association with QoL (Table 7).

Discussion

The current study provides important insights into the potential impact of COVID-19 on the HRQoL of cancer patients undergoing active treatment. The primary finding was a statistically significant difference in levels of fatigue between those with and without a prior COVID-19 diagnosis, with the COVID-positive group reporting higher fatigue levels. This aligns with other research that has documented increased fatigue as a common symptom in cancer patients after COVID-19[14,15]. Such findings suggest the virus may have lingering effects on energy levels and the ability to carry out daily activities, even after the acute illness has resolved. Interestingly, the data also indicated a potential difference in emotional functioning, with the COVID-19-positive group trending towards poorer emotional well-being compared to those without. This is consistent with studies demonstrating increased psychological distress, such as anxiety and depression, in cancer patients with COVID-19[16]. The mechanisms underlying these associations are not entirely clear, but may

involve complex interactions between the physiological impact of the virus, the unique vulnerabilities of cancer patients, and the significant psychosocial stressors introduced by the pandemic. It is possible that the fatigue and emotional burden experienced by COVID-19-positive cancer patients contributes to an overall diminished QoL, though the current data did not find statistically significant differences in other measured domains[17].

Important, the magnitudes of the differences observed, while statistically significant, were relatively modest, with both groups falling within the "mild" to "moderate" range for the affected outcomes. This suggests the clinical relevance may be limited, and that many cancer patients are able to maintain adequate QoL despite the challenges posed by COVID-19[18]. The study findings suggest that COVID-19 may have a specific impact on the physical functioning domain of cancer patients' QoL. This aligns with research demonstrating increased fatigue as a common symptom in cancer patients after COVID-19. While depression severity did not significantly influence most other QoL areas, the data indicate that variations in depression scores, as measured by HAMD, were associated with differences in physical function. This highlights the importance of assessing and addressing depressive symptoms in this population, given the potential implications for physical wellbeing[19]. Further analysis revealed a significant positive correlation between COVID-19-related anxiety and depression levels, suggesting these two mental health factors may be interrelated in cancer patients during the pandemic[20]. Additionally, the study found a statistically significant association between a history of COVID-19 and moderate levels of depressive symptoms. This indicates that a prior COVID-19 diagnosis may increase the risk of clinically relevant depression[21] in this vulnerable patient group. Important, the analysis of the adjusted odds ratio demonstrated a greater likelihood of an association between depression and poorer HRQoL, compared to the association between anxiety and QoL. This underscores the need to prioritize the screening and management of depressive disorders in order to optimize QoL outcomes in cancer patients navigating the challenges of the COVID-19 pandemic[22]. Overall, these findings emphasize the multifaceted impacts of COVID-19 on the physical and psychological wellbeing of cancer patients, with a specific focus on the relationships between infection, depression, and various QoL domains. Continued research and clinical efforts are needed to develop tailored interventions to support this vulnerable population during the pandemic[23].

The present study had some limitations, acquisition of data through telephonic conversation resulting in lack of understanding of patients' attitude and perceptions through non-verbal communication.

Conclusions

The study findings underscore the multifaceted impact of the history of COVID-19 on both health and QoL dimensions. Notably, individuals with a COVID-19 history reported significantly higher levels of fatigue compared to their counterparts without such a history. This finding suggests a potential resilience or adaptation in managing post-viral fatigue among these individuals. However, the study did not observe significant differences in other aspects of health and QoL, indicating that while fatigue may be distinctly affected, broader health metrics remain largely unaffected by COVID-19 history. Furthermore, the research highlighted correlation between depressive symptoms and impairments in physical function, cognitive abilities, and sleep quality, underscoring the pervasive impact of depressive states on multiple facets of well-being. Importantly, the study's data revealed a significant association between a history of COVID-19 and heightened depressive symptoms, which points to a critical need for tailored mental health interventions for this patient group. This underscores the importance of integrating mental health support into post-COVID-19 care strategies to address the specific challenges posed by the virus on mental well-being and fatigue management.

Authors contribution:

Study conception and design: SR,VR.N and RK.P; data collection: S.K, T.S, VK.A; analysis and interpretation of results: M.A, B.S; draft manuscript preparation: VR.N, RK.P and VH.N. All authors reviewed the results and approved the final version of the article.

Compliance with Ethics Requirements:

"The authors declare no conflict of interest regarding this article"

"The authors declare that all the procedures and experiments of this study respect the ethical standards in the Helsinki Declaration of 1975, as revised in 2008(5), as well as the national law. Informed consent was obtained from all the patients included in the study"

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