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The primary caregiver's burden of the oncological patient with palliative needs

SUMMARY

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Introduction

The stated purpose of palliative care is to improve the quality of life of patients , of their families and caregivers . In Romania palliative care services are unevenly spread throughout the country and most of them only for the oncological patients . Thus 76,5% of the patients with palliative needs are taken care of at home and in 85-90% the responsibilities are taken over by a family member .

The primary caregiver, family member or not, who is close to the patient is the person who shares his experiences in relation to the disease and who engages in his physical care and in managing his emotions . Not at all negligible is also the management of social and spiritual problems during the patient care period . A characteristic of the caregiver of a palliative patient is the ambiguity of his situation , as he is at the same time both provider and beneficiary of palliative care . On the one hand , together with the patient , he is part of the central unit on which all the palliative care interventions of the multidisciplinary team are directed, and, on the other hand he is included as " disciple" within this team , being the person to whom many of the palliative actions are delegated . The primary caregiver is the person close to the patient who is actively involved , without being paid , in the patient's care . The most visible tasks are : the managing nutrition related problems and patient's discharges , performing patient hygiene maneuvers, ensuring household tasks, medication administration , performing physical therapy movements if instructed, accompanying the patient to various consultations when needed .

"Caregiver burden" is a more and more frequently encountered notion in literature but not well enough understood . It is a difficult " symptom " to evaluate in clinical practice because , on the one hand patients and doctors focus on the disease , investigations, treatment and resort to palliative care as late as possible or not at all and , on the other hand , each individual (patient or caregiver) has a variety of problem-solving skills and to face emotional and situational challenges . We can say that the burden represents the multitude of responsibilities that appear further to a situation that involves exhausting physical work and leads to physical and moral suffering . The evaluation of the caregiver's burden at the first contact between him and the patient gives us the chance to intervene punctually , " preventively " or " curatively " to anticipate or improve it .

The physical domain of caregiver burden describes changes in the physical functionality, degree of fatigue , changes in sleep quality, reduction of sleep periods , reduction of periods intended for relaxation or for recreation activities and for self-care . More than 50% of the caregivers for patients with palliative needs reported health problems especially heart problems, high blood pressure or joint problems . The most frequent symptoms experienced by the caregiver refer to pain that can range from discomfort to severe pain (95.2%) , insomnia (52.8%) , digestive disorders such as loss of appetite , nausea , vomiting (42.5%) , feeling of general exhaustion (43.4%) . Severe fatigue was reported by quarter of cancer patient caregivers and was correlated with the increased burden of caregiving without a correlation between patient fatigue and that of the caregiver . Physical suffering of different intensities was described especially in the care of patients with non-oncological diseases , due to the caregiver's long request time .

The psycho-emotional disorders of the caregiver appear in 96% of the cases under different aspects : emotional pain , sadness or guilt along with the struggle to accept the situation . Sometimes the emotional state is extreme , manifested by fear , loss of hope , exhaustion manifested by the feeling of wanting to escape from the situation . In more than half of the cases , confusional disorders or delirium appear . Anxiety has been frequently described to the caregivers in the palliative field (61.8%) with the appearance of moderate and severe forms of anxiety in almost half of the cases . Depression has been described in 48.7% from the cases of the primary caregivers and 35 % of them presented manifestations at least once a week . One person out of 10 primary caregivers required the specialized intervention of a psychiatrist . In a quarter of the situations , people can develop a major depressive syndrome the moment the end of life is approaching for the patient and the same percentage still experience severe depression one year after the caregiving process ended . The prolongation of the symptomatology long after the completion of the care process , shows the intense and long-lasting influences on mental and physical health that the care of a patient with palliative care has on the one involved with the obvious risk that these people will develop various psycho-somatic ailments in the future .

The existence of the dependence between the physical and emotional burden was observed , being compared by Fitzimons (2018) to a rollercoaster having its roots in :

- ✓ inadequate understanding of palliative care through poor communication ,
- ✓ uncertainty of the evolution of diseases , especially non-oncological ones ,
- ✓ lack of continuity of care at home and
- ✓ poor predictability that makes it difficult to draw up an intervention plan .

The patient's burden is mostly represented only by his own disease , with all its implications , while the family burden or that of the primary caregiver from the family is connected to the care provision at home , to social aspects , transport of patient to hospital , to the assistance from the wider family circle and to the socio-economic aspects . Of all the social challenges , the most demanding for the primary caregiver is the decision-making process , especially when the final state approaches . The multitude of responsibilities and long time allocated to the patient's care caused the caregiver to greatly reduce the schedule at the workplace , sometimes even to give up the workplace or to refuse employment from the start at that moment . All these determine the decrease of the own income , the income per family member or even its cancellation . The analysis in real terms of the costs related to the patient's illness , highlights a financial cost that most often exhausts the family and determines an extra burden on the caregiver with the inability to sometimes manage the situation .

Almost half of the caregivers dedicate their time entirely to the patient care , and almost a third allocate more than 6 hours a day to this activity , which leads to the lack of time for rest or the reduction of time spent with other family members or with friends . The lack of social support is perceived as a high degree of burden for the caregiver and it is a predictive factor for the family's reaction to the person involved in the care . The family feels neglected and abandoned , which has a negative effect on the caregiver's health by increasing dissatisfaction with one's own person .

Spirituality is the dynamic and intrinsic element of humanity through which people seek meaning and purpose of life and experience the relationship with oneself , with family and with community . Spirituality is expressed through beliefs , values, traditions and certain practices that differ from one community to another . The reduced degree of spirituality leads to the perception of a higher degree of burden and this one is statistically significant associated with the occurrence of psycho-emotional disorders ($p < 0.001$) [100] . The high degree of spirituality has a protective effect for the emotional decompensation of the caregiver who spends more time with the patient and is associated with a decrease in the frequency and level of anxiety and depression of both the patient with palliative needs and his caregiver . The interrelationship between the psychological , social and spiritual domains can improve the caregiver's ability to face the challenges arising in the care of a patient with palliative needs and spirituality represents an important role in preventing or reduction of burden perceived by him .

The burden of care may be appreciated as a balance between the negative perception of all the responsibilities arising in patient care and the positive aspects that tend to reduce the burden . Among the positive aspects that may influence the caregiver's perception on burden and can balance the scales are the following : satisfaction of a well done job , the ability of the caregiver to face the new appeared situation , the general well-being of the family , own sense of usefulness for the patient , self-efficacy and the ability to manage the quality of care , the quality of the relationships between the patient , caregiver and the care team , the increased level of self-esteem , adequate social support . The caregiver's ability to find meaning in what he does through positive reviews towards him and through religious faith , will lead to appropriate actions to face tense situations and to feel pride and meaning in his actions .

The tools for the evaluation of palliative caregivers were initially developed for research purposes and will be used in clinical practice . They are unidimensional and evaluate only one aspect of the burden or multidimensional containing items that evaluate more dimensions of the burden .

The perception of the quality of life is different from one individual to another , being correlated with the personal , cultural values , level of education , personality and age . The person involved in the care of a patient with progressive life-threatening disease experiences a complex situation with numerous

responsibilities that can lead to physical , emotional , social and spiritual overload . To all these is added the primary caregiver's tendency to put all his needs in the background , putting the patient first . Gradually appears his exhaustion , personal dissatisfaction regarding the act of care , desire to escape from the situation and uncertainty . It is the moment when the caregiver transforms himself from a " hidden patient " with latent impairment into a " real patient " .

Ensuring continuity of care at home and of training interventions for the caregiver regarding care techniques , management of symptoms , adverse effects of the medication , positively influenced the caregiver's life quality . Information about the disease , understanding the disease and the diagnosis can significantly improve the caregiver's life quality and to reduce the care burden . Educational sessions for physical and mental self-care , learning relaxation techniques , breathing techniques , emptying the mind , optimistic attitude , prove their effectiveness in improving the caregiver's life quality . Learning the caregivers to solve problems by adopting a positive attitude , defining the problem , finding solutions and alternatives and preventing consequences , had a benefic effect on the quality of life in the social , financial and physical field .

The factors that can lead to an increase in the quality of life are especially those related to communication with the team , of information about disease , treatment , adverse effects but mainly co-opting the caregiver in the process of drawing up the patient's management and evaluation plan . The state of blockage in communication increases uncertainty and caregiver's anxiety , decreasing his quality of life . The quality of intra-family relationships and the involvement of other family members lead to an increased quality of the caregiver's life . The relaxation time as well as the relaxation techniques will be able to positively change the caregiver's state , the result being a better care .

Personal contribution

Objectives

The hereby research aimed to quantify the primary caregiver's burden , to describe its component elements and to highlight the correlations between the caregiver's burden and his anxiety , depression and quality of life . The practical curiosity was to finally answer if this burden differs from the caregivers of the patients with oncological disease compared to those who care patients suffering from non-malignant diseases .

The aim of the study was to identify and analyse the burden of a primary caregiver for a patient with palliative needs .

The main objective was represented by the comparative estimation of the primary caregivers' burden for the patients with chronic progressive oncological and non-oncological disease in the stage of palliative care .

The secondary objectives leading to a detailed evaluation of the care burden were the following :

1. Identification of physical , psycho-emotional , social and economic aspects of the burden of care for a patient with palliative needs . In-depth understanding of the components of the burden experienced by the primary caregiver in assisting the patient with chronic progressive disease .
2. Identification of differences and comparative analysis between the burden of care of a patient with malignant disease and of a patient with non-malignant disease in the palliative care .
3. Identification of impact the burden of care has on the psycho-emotional state of the primary caregiver
4. Identification of impact the care burden has on the primary caregiver's quality of life .
5. Identification of the way in which the complexity of the patient's treatment plan influences the burden of care .

Thesis structure

The paper consists of 2 parts : a general one that represents the theoretical support containing information from literature about the definition of the primary caregiver and of the burden , about the components of the burden of care and about the impact it has on the person involved in the care and a special one that contains the main contributions to the research for the subject proposed by this thesis . The special part is in its turn made up of four parts : one that describes the characteristics of the subgroups of primary caregivers , one that measures the burden and identifies its component aspects , one that studies the impact of burden on the psycho-emotional disorders , one that measures the impact of burden on the caregiver's quality of life and the last one that establishes the relationship between the burden and the therapeutic plan of the patient . At the end of the paper I highlighted the elements of novelty and importance the research of the subject brings as well as the further research directions .

Study 1

Study 1 had the aim to identify and measure the components of the burden of the primary caregiver of a patient with palliative needs . The evaluation of subjects was carried out with a questionnaire called Burden Scale for Family Caregivers made up of 28 items that measure three fields of the burden : the physical , psycho-emotional and social field . The application of the questionnaire was done at the time of being included in the study , which coincided with the initiation of palliative care , then the subjects were monthly evaluated for a period of 3 months .

Study 2

The aim of study 2 was to evaluate the psycho-emotional changes that affect the primary caregiver of the patient in palliative care and their correlations with the type of pathology of the patient cared and with the burden degree accumulated by the primary caregiver . In order to evaluate the psycho-emotional disorders I used the Hospital Anxiety and Depression Scale (HADS) that measures the anxiety and depression level of the subjects . The evaluation was done at the time when being included in the study and monthly for a period of three months . In the case of patients who left the study due to death , the evaluation of the primary caregiver two months after the patient's death brought information about the evolution of the emotional state after the care process ended .

Study 3

Study 3 aimed to highlight the way in which aspects of the quality of life change in persons who care patients with palliative needs . To measure the quality of life was used the instrument validated on the general population called Medical Outcomes Study (MOS-SF36) . This questionnaire with 36 items is filled in by each primary caregiver at the initial moment that corresponds to the initiation of palliative care for the patient and then monthly for a period of 3 months . MOS-SF 36 evaluates 8 dimensions of the quality of life : physical functionality (FF), limitation of the person's role due to physical health (LF), limitation of the person's role due to emotional problems (LE), social aspect (SOC), pain (D), perception on his health in general (SG), vitality/energy/fatigability (V) and emotional state (EM).

Study 4

The aim of the study was to evaluate the complexity of the treatment plan for the patient with palliative needs , of the one with oncological disease and of the one with non-oncological disease , and understanding its impact on the burden of the primary caregivers of such patients in a country where the palliative care at home almost doesn't exist . The care burden was evaluated using the validated instrument , Burden Scale for Family Caregivers (BSFC) . To evaluate the complexity of the treatment plan that the patient had at home , all the drugs administered at home were registered according to drug classes and specific ways of administration , frequency of administration , additional recommendations referring to the way of administration . The complexity of the treatment plan was quantified with the help of an instrument called Medication Regimen Complexity Index (MRCI) . This grid assessed the treatment plan taking into account and quantifying three aspects : the way of

administration (section A), the number of preparations , dosage , frequency of administration including the need to administer the drug in need (section B) as well as other additional recommendations on tablet trituration , fragmentation into smaller units , the relationship with the diet or administration with a certain schedule or depending on certain scales of evaluation (section C) . The evaluation of the burden and of the treatment plan was done the moment the patient was included in palliative care so that all information obtained showed the burden corroborated with the complexity of the therapeutic plan administered by the caregiver at home before the intervention of the team specialized in palliative care .

Research methodology

In the study were included the patient- primary caregiver pairs that presented themselves in the Palliative Care Compartment of the Municipal Hospital Campia Turzii within the period 1st February 2019-31st January 2020 . The eligibility criteria applied were : age over 18 , knowledge of the Romanian language , lack of pathologies to change cognitive function , written consent to take part in research .After enrollment , the subjects were divided into two groups : the group of persons who care cancer patients and the group of persons involved in the care of patients with non-oncological disease .

Results and discussion

In what the group of patients is concerned there are statistically significant differences between the subgroup of cancer patients and those with non-oncological disease regarding four characteristics : age , degree of dependence on care , number of associated diseases and the moment of initiating palliative care compared to the onset of the disease . The cancer patients are statistically significant younger than the patients with non-oncological disease (average age : 72.32 ± 11.90 versus 78.38 ± 9.98 ; $p=0.001$) . Almost half of the patients with non-oncological disease who come to the the stage of palliative care have at least 5 related comorbidities compared to those with oncological disease , which increases the number of care needs (42.86% versus 33.76%; $p=0.04$) . The moment the palliative care was initiated , most of the patients with non-oncological disease were totally dependent on the caregiver , the difference between the two groups being statistically significant (96.83% versus 72.73%; $p=0.001$). The period from diagnosis to access palliative care differs greatly from one case to another , the median being 1098 days for the patients with non-oncological diseases , 283 days for the cancer patients , respectively . In the case of patients with non-oncological diseases , the period from the diagnosis to the inclusion in palliative care is 3.84 times bigger than in the case of cancer patients ($p=0.001$).

The most frequent oncological pathologies were : digestive tract cancer (25%) , bronchopulmonary cancer (14%) and breast cancer (13%) . The degenerative brain pathology is the most frequent non-oncological disease , so that 64% of the non-oncological patients hospitalized were with dementia of various advanced etiologies . In what the frequency is concerned the stroke follows (27%) with different degrees of sequelerity and the congestive heart failure class NYHA IV (6%) .

The two subgroups of caregivers are homogeneous and they do not significantly differ from each other . In almost 90% of the cases a family member took over the care of the patient with palliative needs and one of ten patients faces the suffering alone , the care being taken by a person outside the family (friend , neighbour) . Rare are the situations in which the patient's sister/brother is involved in the care (3.90% in the oncological group and 3.18% in the non-oncological group) or his nephew/niece (6.5% in the oncological group and 6.35% in the non-oncological group). The age difference between the patient and the primary caregiver shows that the next generation of the family is most frequently involved in the care, so that in half of the situations the patients' care is taken over by the patient's son or daughter (51.95% in the group of oncological patients , 53.97% in the group of non-oncological patients , respectively) and in a quarter of the cases the care is ensured by the life partner (25.97% in the group of oncological patients , 23.8% in the group of non-oncological patients , respectively). More than two-thirds of the primary caregivers are women (68,26% versus 70,13%; $p=0,81$), circumstance explained by the woman's proven ability to provide all domestic chores : housekeeping , food preparation , childcare and patient care , respectively . The caregiver's occupation is an important parameter as it is directly related to the availability of time for the patient's care . It was observed that almost half of the caregivers are retired (45.45% in the oncological group , 50.8% in the non-oncological group ,

respectively), being much more available in terms of time allocated for care . Caregiver's home is a factor that influences on the one hand the quality of care , but , on the other hand it may be a burden for him . It was observed that in more than half of the cases the primary caregiver and the patient had the same home which facilitates care by saving travel time (49.35% in the oncological group versus 63.49% in the non-oncological group). The time spent for patient's care is an important parameter for the patient that has many needs and care requirements but also for the caregiver , who besides the cared person has his own family and life . Over a third of the caregivers spend more than 10 hours for the patient's care (37.67% in the oncological group , 47.62% in the non-oncological group , respectively). Yet only 7.79% of the caregivers for the cancer patients and only 4.76% of the caregivers for non-oncological patients gave up the job . The small percentage of job waiver is due on the one hand to the fact that the large share of caregivers was with retirement status and on the other hand due to the personal choice to use the time allotted to the other family members before using the time allotted to job.

At baseline , the values show that the burden is statistically significant higher to those who care a patient with non-oncological disease than to those who care a cancer patient (45.14 ± 14.45 versus 36.52 ± 15.05 ; $p=0,01$) due to the longer period in which the caregiver manages at home the whole situation and to the higher degree of dependence for the oncological patient that accesses faster a palliative care service .

Compared to the non-oncological group , cancer patients have a greater variability of symptoms and needs so that these are reflected in the oscillating evolution of the caregivers' burden throughout the palliative care . The dynamics of the burden in the oncological group change statistically significant from one month to another , the registered burden being significantly lower at baseline [(36.52 ± 15.05) in the oncological group versus $(45.14 \pm 14,45)$ in the non-oncological group ; $p=0,01$]. As the disease evolves , symptoms of different intensities appear so that the caregivers have experimented a burden that statistically significant varies from one month to another (36.52 ± 15.05 at T0 compared to 45.58 ± 14.11 at T1; $p=0,002$, 37.65 ± 16.10 at T2 compared to 47.08 ± 18.86 at T3; $p=0,001$, respectively) . At the moment T1 compared to T2 was observed a statistically significant decrease of the burden (45.58 ± 14.11 at T1 at 36.65 ± 16.10 at T2; $p=0.001$) that could be explained through the positive effect of the palliative care by obtaining a better control of the symptoms .

In the case of the patient with non-oncological disease , the burden gradually increased without statistical significance from one month to another . The difference 3 months after the initiation of palliative care was highly statistically significant (45.14 ± 14.45 la T0 versus 56.69 ± 15.44 at T3 ; $p<0.001$). In the last month of evaluation is observed a statistically significant increase (56.69 ± 15.44 at T3 compared to 47.43 ± 14.45 at T2 ; $p<0.001$) probably due to the evolution towards the terminal state . We can talk about the existence of a burden set in the case of the care of a non-oncological patient due to the caregiver's exhaustion , but keeping the increasing trend throughout the three months .

BSFC score recording generates an objective , measurable picture of the care burden , a multidimensional entity that has to be separately described and measured for specific and efficient intervention .

In both groups it was observed that the burden evolution under all aspects , increased from one month to another but not always with statistical significance .

At moment T0 , that corresponds to the initiation of palliative care , the caregivers of the patients with non-oncological disease are much more physically exhausted due to the previous long period of care for the patient (9.54 ± 3.69 versus 7.69 ± 3.77 ; $p=0.004$) and they perceive much more emphasised its effect on the worsening of their health (1.59 ± 1.15 versus 1.08 ± 1.06 ; $p=0.008$) . However , the caregivers from both subgroups strive to perform their tasks during care . Throughout the three evaluation months it is observed a statistically significant increase of the physical exhaustion both of the caregivers of the oncological patients and of those of the non-oncological patients ($p=0.02$ versus $p=0.04$).

The caregivers from the group of oncological patients perceive more strongly the deterioration of their own health ($p=0.03$) during the care period , due to the events that are happening much faster ,

compared to the caregivers of the non-oncological patients that have time to adapt themselves to the requirements that appeared .

The desire to get rid of the situation is statistically significant higher in the group of non-oncological patients compared to the oncological ones at baseline (2.13 ± 1.08 versus 1.78 ± 1.03 ; $p=0.05$) as well as at the 3 months evaluation (2.83 ± 0.57 versus 2.38 ± 0.87 ; $p=0.01$). It is also observed that throughout period of the care process , the overload of the caregivers from both groups causes the significant increase of the desire to give up ($p=0.03$ in the non-oncological group , $p=0.04$ in the oncological group , respectively).

As the disease evolves and the care needs increase , the relationships between the caregiver and the patient or other people around are tense , statistically significant more in the group of oncological patients (1.96 ± 1.76 versus 3.15 ± 1.99 ; $p=0.03$).

The feeling of discontent appears at baseline more frequently and statistically significant in the caregivers of non-oncological patients due to physical and emotional exhaustion (3.81 ± 1.6 versus 3.06 ± 1.84 ; $p=0.01$) but throughout the care period it increases in both groups .

The period of time used for oneself by the caregiver is significantly less for those who care non-oncological patients compared to those who care cancer patients (3.92 ± 1.44 versus 3.17 ± 1.72 ; $p=0.007$). It is observed that for the caregivers who care cancer patients , as the disease evolves , the care requirements increase , the period of time for oneself significantly reduces (3.17 ± 1.72 at T0 versus 4.15 ± 1.6 at T3; $p=0.045$). This parameter determines the reduction of the relaxation time and giving up future plans for the caregivers of both groups but significantly higher in the group of non-oncological compared to the group of cancer patients (3.30 ± 1.95 versus 2.16 ± 1.98 ; $p=0.001$). The standard living significantly reduces throughout the care period of the non-oncological patients (1.95 ± 1.02 at T0 versus 2.58 ± 0.99 at T3; $p=0.045$) and it is significantly reduced compared to the caregiver of the oncological patient (1.92 ± 1.02 in the non-oncological group versus 1.44 ± 1.11 in the oncological group; $p=0.006$)

We talk about how difficult it is to care a patient with palliative needs but its objective identification did not enter the usual medical practice . The medical literature is rich in describing the measurement instruments for the burden of care . Such an instrument is the " Scale of evaluation of the burden at home " (BSFC) with 28 items , especially used in research .

Considering the homogeneity of the two groups of caregivers , it is observed that the differences of the burden depend on the patients' characteristics . The severity of the disease , the associated comorbidities will increase the number of needs and implicitly the burden for the caregiver . More than half of the caregivers of the palliative patients reported a quantity of physical activities that exceeded their ability to perform them and especially that these did not significantly reduce when the patient was hospitalized .

The significantly higher patient dependence in the non-oncological patients , loneliness and time from diagnosis to initiation of palliative care are other three factors that influence the burden of care in what its increase is concerned . During the care process there is a desire to escape from this situation being obvious the physical and mental exhaustion of the primary caregiver .

The non-oncological diseases , due to the fluctuating trend , come in palliative care much later than the oncological diseases , the result being the caregiver's physical and emotional exhaustion under multiple responsibilities . From the moment of accessing palliative care , the level of their burden is a moderate to severe one with increased risk of developing psychosomatic pathologies . If other pre-existing conditions or previous care experiences for other members of the family are combined , the subjective burden will be augmented . In addition , the burden records a plateau during the three months of evaluation . This is especially due to the caregiver's exhaustion degree at the too late moment of initiating the palliative care . The many care needs are increasing which is confirmed by the statistically

significant increase of the burden between the initiation of the palliative care and the value obtained after three months of evaluation .

The oncological diseases have a faster evolution , the care needs become more obvious for the health system through pain symptoms of different intensities , digestive or neuropsychiatric symptoms . The caregiver of an oncological patient will be in the attention of the medical system faster than that of the non-oncological patient . In his case , too , the physical exhaustion , the psychoemotional changes occur during the course of the disease . The dynamics of the evolution of the burden score , during the care of a cancer patient , increases statistically significant as the disease evolves . Paradoxically , it was observed that after the first month since the intervention of the specialized team in the unit with beds , the degree of the burden significantly decreased due to the rest period needed by the caregiver for energy recovery . This comparative dynamics of the burden of care depending on the oncological or non-oncological pathology must be interpreted considering also the limitation of the study through the small number of the final sample .

Due to dependency and care needs of a non-oncological patient , the physical exhaustion is significantly higher leading to the desire to escape from the situation and give up . To all these are added the lack of support , uncertainty or misunderstanding of the prognosis that lead to the postponement of the future plans and the decrease of the living standard .

The importance of assessing the burden of the primary caregiver becomes obvious in palliative care and the implementation in practice of a validated instrument is a necessity . The instrument used in this research must be validated on population cohorts .

The assessment of anxiety and depression in primary caregivers showed different degrees of intensity . At the time of initiation of the palliative care only 12.69% of the primary caregivers for non-oncological patients and 18.18% of those who care oncological patients recorded a normal score of anxiety . About two thirds of the primary caregivers are with moderate or severe anxiety at moment T0 (66.45% in the non-oncological group and 61.53% in the oncological group) . The percentage of subjects with severe anxiety is higher in the non-oncological group (41.06%) compared to the oncological one (27.77%) .

Just one month after the initial assessment , the share of those suffering from moderate and severe anxiety increases , reducing the difference between the two groups (72% in the non-oncological group compared to 69.22% in the oncological group) . The percentage of the patients with severe anxiety tends to equalize between the two groups (56% in the non-oncological group compared to 53.84% in the oncological group) which shows that the evolution of the oncological disease leads to the increase of anxiety regarding the management of symptoms and care tasks .

The number of persons involved in the care that show elements of depression is reduced compared to those with anxiety phenomena , 20.63% in the non-oncological group and 36.36% from the oncological group that recorded normal values . At the moment the palliative care was initialized , the depression of moderate and severe level appears in slightly more than half (52.37%) of the caregivers of the patients with non-oncological disease and even less (42.85%) in those who care cancer patients . The severe level of depression was more frequently recorded in the non-oncological group (30.15%) compared to the oncological group where it is much lower (18.18%) . The percentage of subjects with moderate depression is almost the same (22.22% in the non-oncological group and 24.67% in the oncological group) .

After one month , a more accelerated dynamics was observed in the oncological group where the percentage of subjects with severe and moderate depression increased very much from 42.85% to 65.38%, a percentage that exceeded the value recorded in the non-oncological group at a month (64%). In addition , it was observed that the proportion of subjects with severe depression is maintained approximately the same in the non-oncological group (30.15% at moment T0 compared to 32% at moment T1), the increase being more obvious in the oncological group (18.18% at moment T0 compared to 26.92% at moment T1).

By analysing the average values of anxiety and depression during the three months , it was observed that the psycho-emotional disorders that impact the primary caregiver do not significantly differ between the two groups but record changes in dynamics throughout the period .

In the group of those who care patients with non-oncological disease it is observed that during the care the intensity of anxiety increases without statistical significance but after the patient's death a significant decrease is recorded (12.87 ± 4.68 at the initial moment and 9.90 ± 5.39 two months after the patient's death; $p=0.001$). In the group of those who care cancer patients, it is observed a significant increase of anxiety during the care (11.97 ± 4.56 at moment T0 at 13.63 ± 5.18 after three months; $p=0.03$). After the death of the oncological patient, the anxiety state of the caregiver decreases very much (13.63 ± 5.18 at moment T3 at 8.75 ± 4.80 two months after the patient's death; $p=0.001$). Noteworthy that two months after the end of his role, the primary caregiver had an average anxiety score that ranged between 9.90 in the non-oncological group and 8.75 in the oncological group which shows that he remains at risk of developing psychosomatic pathology in the future.

To highlight if there is a connection between the burden of care of the palliative patient and the anxiety and depression of the primary caregiver the Pearson test was used for the whole group of 140 primary caregivers. A moderately tight directly proportional correlation was observed in both cases of psycho-emotional disorders ($r=0.52$ in the case of anxiety and $r=0.60$ in the case of depression). In both situations the correlation between the burden of the caregiver and his anxiety, depression respectively, was significant from the statistical point of view. ($p=0.001$)

Palliative medicine integrates the somatic and psychological aspect that appeared in the evolution of advanced incurable diseases observing that the two aspects are mutually interdependent. Many of the somatic aspects of the disease – pain, headache, blood pressure value – have a component of anxiety.

Psychiatry differentiates between psychosomatic disorders in which the psychological factor has an important role in the emergence, manifestations, evolution and treatment of physical diseases and somatoform disorders in which the psychological factor represents the only cause of the physical disease. In the case of patients in an advanced stage, when the palliative care is needed, it is very difficult to make this distinction, especially with the evolution of the disease and the general condition of the patient depend also on other factors such as thoughts and personal feelings, previous mental state, intrafamilial relationships and uncontrolled physical symptoms.

The most frequently met psycho-emotional disorders are: anxiety, panic attack, social anxiety disorder, psychosomatic symptomatology and the posttraumatic stress syndrome. Of these, in 25-40% of the primary caregivers experience anxiety and depression that increase in intensity during the care having a decrease of the score after the patient's death.

The factors that influence the level of anxiety of the caregiver are: aspects related to the care at home management of symptoms, his physical and mental preparation for responsibilities, degree of patient's dependence on care, lack of social support. To all this is added the pressure from one's own family due to the responsibilities and natural events that follow from everyday life. An increased risk of psycho-emotional disorders are found in women, the advanced age of the caregiver together with the unsatisfactory relationships between family members.

The anxiety of the primary caregiver increases statistically significant during the evolution of the disease without being influenced by the patient's type of pathology, not statistically significant differences being observed between the group that cares patients with nononcological disease (66%) compared to those who care cancer patients (61%). Data from the literature show that 66% of the caregivers experience a high level of anxiety before the moment of the patient's death.

Depression has a different frequency within the primary caregivers, ranging between 16-67%, our study showing that it is almost 10% lower than the frequency of anxiety. In response to such stress their caregivers use a variety of strategies to manage the disease and related symptoms. The use of such adaptation strategies is associated with decreasing the burden, increasing the quality of life, reducing the symptoms of depression and anxiety, understanding diseases and end-of-life care. The factors associated with the occurrence of depression in the primary caregivers are: age, level of education, anticipatory suffering of the patient's moment of death, lack of psycho-social support, change of intrafamilial relationships.

The period of time following the patient's death shows a statistically significant reduction of anxiety and depression among the caregivers ($p=0,001$) but maintaining an "alert" score that can determine the person to decompensate. Such a period may cause in 27% of the cases severe anxiety and even more severe depression (35%) within the persons who have gone through a period of care for a family member.

The burden perceived by the primary caregiver of a patient with palliative needs is statistically significant related to anxiety and depression, a fact proved by other previous studies both in the care of patients with oncological and non-oncological diseases. Their psycho-emotional disorders strongly influence the quality of life even more than the physical burden being a problem of public health. However, only 4% of such persons receive psychological support during the care and even less after the death of the patient.

It is observed that all aspects of quality of life are decreasing as the care process of the non-oncological patient progresses. Moreover, the caregiver of the patient with non-oncological diseases is totally physically exhausted in the moment when the patient is taken over by the specialized team, with the total limitation of the role due to physical problems.

The limitation of the caregiver's role due to emotional problems remains totally affected during the care probably due to lack of targeted interventions for the primary caregiver who still remains a "hidden patient". Statistically significant differences are observed in the emotional return with the possibility of resuming the role in society ($p=0,002$), physical recovery by increasing vitality ($p=0,049$) and social return ($p=0,01$) two months after the care process ends. At that moment, too, the return of physical functionality (70/100), body energy (51.29/100) and subjective perception of one's own state of health (50/100) is at a value slightly above that from the moment when the patient was taken over by the care team. Such values represent only half of the maximum value showing that the physical, emotional overload is important and these people will no longer have a quality life similar to that previous the care process.

In the case of caring for a patient with cancer, the initiation of palliative care is earlier than in the case of non-oncological diseases because the pain symptomatology is much accentuated, requiring evaluation and intervention. The physical functionality of the primary caregiver is very little affected (from 80/100 to 70/100) but the emotional state and limitation of the caregiver role, respectively, due to the emotional impact is much more affected (from 33.3/100 to 0/100). The emotional return is statistically significant after two months since the care process ended (66.7/100; $p=0,05$). The perception of one's own state of health was affected, but the return two months after the patient's death does not even return to the initial value. This represents a predictive factor for morbidity in the future of the primary caregiver who becomes the future patient of the health system.

The social life is similarly affected in the non-oncological group with the statistically significant return two months after the patient's death ($p=0,03$).

The pain felt by the caregiver may be due to physical effort and may be exacerbated by the emotional impact that occurred during the care. It is a factor that leaves a mark on the quality of life of the assessed person. The pain assessment places it at the level of moderate intensity and remains in the plateau with insignificant variations during the 3 months of evaluation. Most of the time, it is neglected by the primary caregiver because his attention is to fulfil tasks towards the cared for. Two months after the patient's death, the pain plateau continues being the expression of psychosomatic affections developed and neglected by them.

The emotional domain of the quality of life includes the emotional state and the limitation of the person's role due to the emotional problems. Although at the initial moment, the emotional state of the subjects from the two subgroups was similarly affected (48.32/100 in the non-oncological group versus 52.16/100 in the oncological group) it was observed that the limitation of the role of the person involved in the care of non-oncological patients due to the emotional problems was completely affected

compared to the oncological group ($p=0,007$). After three months , even if the emotional state is maintained in the plateau , the emotional problems determine the total loss of the care roll in both groups .The return of the emotional state two months after the patient's death , is slightly over the initial value being statistically significant (56/100 in the non-oncological group and 60.08/100 in the oncological group). The resumption of the roles in society of the primary caregivers was statistically significant for both groups ($p=0,002$ in the non-oncological group , $p=0,05$ in the oncological group , respectively)

The vitality and perception of one's own health were significantly decreased in the non-oncological group, but in both groups, the values were below half of the maximum value, which was directly related to the physical and emotional status declared by the caregivers. In terms of vitality, there were no statistically significant differences between the two groups. The perception of general health was more affected in the group of those who cared for non-oncological patients ($p = 0.02$ at the initial moment and $p = 0.07$ for the last evaluated value).

According the social dimension, the multitude of responsibilities and the increased time spent caring for the loved one lead to numerous social restrictions that did not statistically significantly differ between the groups but were significantly modified during care ($p = 0.01$ and $p = 0.03$, respectively).

In the group of primary caregivers of cancer patients, the quality-of-life was affected in all aspects, but there was statistically significant decrease and limitations in usual roles due to the physical and emotional problems. This shows that cancer patient's caregivers are usually exhausted when accessing a palliative care service. At two months after the patient's death (Tf) these parameters increase but no more than 60% of the normal value. The emotional changes of the caregiver's mental status can develop toward psychological diseases such as depression and anxiety.

In the non-cancer group of primary caregiver's the situation is worse with severe limitations in usual role due to emotional and physical problems showing exhaustion of the caregiver. In addition, energy/vitality of caregivers is decreased during the care these patients. An explanation could be that the long period of care affects the physical condition of the caregiver, with the appearance of bodily pains, and the emotional exhaustion with the decrease in energy.

The difference between oncological and non-oncological group showed that their perception about general health is significant decreased in group of patients with non-malignant illnesses. The multitude of responsibilities and the increased time spent caring for the loved one lead to numerous social restrictions that did not statistically significantly differ between the groups but were significantly modified during care.

The therapeutic plan contains medication administrated by parenteral and non-parenteral way. The non-parenteral administration of medication is easy for caregivers and no additional skills needed. Parenteral medication is usually administered in units with beds or at home, but, by specialized staff. As such, we discussed parenteral administration separately from the other. The number of preparations administered per day includes the totality of tablets, suppositories, patches administered some of them once a day others more times a day. The average of the administrations was of 6.95 ± 5.06 . The parenteral administrations refer to antibiotics, anticoagulants, rehydration solutions, analgesics of various types. On average, there were registered 5.76 ± 3.42 parenteral administrations per day.

The correlation between the number of non-parenteral drugs administered per day and the burden identified with the caregiver was significantly statistic ($p=0.044$) but with weak correlation directly proportional ($r=0.16$)

The correlation between the number of parenteral administrations and the caregiver's burden is not significantly statistic ($p=0.073$) due to the fact that this is the attribute of the specialized staff either in the units with beds or by the home-care team. The cost of medication/day was on average of 21.90 ± 13.9 and the cost of sanitary materials of 4.49 ± 1.46 The correlation between the cost of the daily treatment for the patient and the primary caregiver's burden is not significantly statistic ($p=0.54$) and with a weak correlation directly proportional ($r=0.05$)

Sometimes the medication cost per month may exceed the patient's income per family member which shows the burden of all the family members. On average the spending on medication represents about half of the monthly patient's spending for care and the correlation between the daily spending on

medication and the estimated spending by the patient for patient's care is significantly statistic ($p=0.001$)

The evaluation of the treatment complexity by MRCI shown no significant differences between the two groups ($p=0.66$). The assessment of the daily non-parenteral units found a significantly higher number for non-oncological patients compared with cancer patients (8.25 ± 4.94 vs. 5.89 ± 4.93 ; $p=0.004$). Regarding parenteral administered drugs, the mean daily units was higher in cancer patients (6.51 ± 3.48) vs. non-cancer (4.84 ± 3.12), the difference being statistically significant ($p=0.002$). The mean score of the burden on the family caregiver was higher in the non-oncological group compared to the oncological group (45.14 ± 14.45 vs. 36.52 ± 1), the difference being statistically significant ($p=0.001$)

Caregivers' burden score is statistically significantly correlated with the complexity of the medical plan in both groups ($p=0.032$ and $p=0.012$ respectively) as shown in figure 4. The heavier burden in case of non-cancer patients is accounted for by the higher number of daily non-parenteral units, which fall into the responsibility of the family caregiver. Also, the median time from diagnosis to initiation of palliative care was significantly longer than in case of non-cancer patients (1098 days vs. 283 days; $p=0.001$). During this period all the responsibilities, among which drug administration, lie with the family caregiver.

The most frequently used classes of drugs in non-cancer patients are: cardiovascular (270 vs. 150; $p=0.0001$), neurological (101 vs. 55; $p=0.0001$) and psychiatric (89 vs. 71 $p=0.05$). In the cancer group, the most used, with high statistical significance, are corticosteroids (29 vs. 5; $p=0.0001$), opioids (72 vs. 3; $p=0.0001$) and gastroenterological medication (188 vs. 79; $p=0.0001$) as shown in figure 5

Analgesic drugs were used differently in the two groups (Figure 6). Thus, while non-opioid pain killer were similarly administered in both groups (34 vs. 54 $p=0.11$), weak and strong opioids have been more frequently given for pain control in cancer patients (5 vs. 72 $p=0.0001$).

This research confirms that the non-oncological patient's primary care experienced an increased level of burden due on the one hand to the very long period between the time of diagnosis and the initiation of palliative care and on another part of the total dependence present in most patients in this category. Almost half of the family caregivers of non-oncological patients have a moderate burden score,¹⁵ depending on the patient's needs, degree of dependence and therapy prescribed.¹⁶ Our study confirms that in case of non-oncological patients, the length of time from diagnosis to professional palliative intervention is very long, most patients being totally dependent, therefore more than half of the primary caregivers experience high levels of burden. In case of oncological patients, access to the specialized palliative care unit occurs sooner, therefore the family caregiver is able to manage care without being overwhelmed by the task.

An important part of the care is managing the therapeutic plan, from obtaining the medicines to administering them. The treatment regimen includes a number of prescribed drugs, all with well-established times and ways of administration. Over half of the patients (57.9%) have very complex treatment plans, which increases the burden on the patient.¹⁷ The family caregiver is directly involved in managing this plan. Our study showed a statistically significant difference between the burden and the complexity of the treatment plan. Moreover, the recommendation to administer a certain drug "only when needed" adds to the caregiver's stress, due to the uncertainty of correct administration.

Unwanted side effects of medication, which may result in its discontinuation,¹⁸ as well as administration errors,^{15,19} are the main causes of the stress experienced when providing care for a loved one, with negative consequences for the patient. Also, polypharmacy is due to the association of several conditions and cross consultations of different medical specialties, which loads the treatment regimen. A fact noted at the beginning of palliative care is that a cancer patient has an average of 10.18 drug items per day, while a non-cancer patient has 11.55 drugs per day to be taken at home. A retrospective study has imperatively drawn the attention on the necessity to reduce polypharmacy through repeated evaluations and renounce useless and ineffective medication, to adapt the treatment plan to the disease stage, which may be performed by palliative care professionals following holistic assessment.^{20,21}

The caregiver's burden may be considerably reduced by the reassessment of care objectives,^{19,25} giving up useless medication,²⁶ using guidelines for deprescribing useless medication,²⁶ reassessment of drug

interactions,¹⁸ simplifying administration regimen,¹⁸ information about drugs and possible side effects,^{25,27} as well as knowledge about the patient's disease and especially management of symptoms.^{28,29}

The study raises concerns about potential excessive drug prescribing for complex patients with multimorbidity and potential lack of collaboration between different clinical disciplines working in isolation. Palliative care seems to need to take on a coordination role in terms of integrating various professional interventions and a supportive role for family members.

General Conclusions

1. The burden of care is a multidimensional entity with folow aspects: physical, psycho-emotional, social and spiritual.
2. The caregiver's burden is significantly higher for persons who care patients with non-oncological diseases than persons who care patient with cancer
3. The primary caregivers experience significant increase of their burden during the care process and this is not depend of the type of disease.
4. The primary caregivers who care fo patients with non-oncological diseases are much more physically exhausted and have much lower standard of their life compared with the caregivers for patients with cancer.
5. Psycho-emotional exhaustion and impaired relationship betwwn patient and caregiver or patient and members of professional team are the aspects that changed in care for oncological patients than non-oncological patient.
6. The percentage of primary caregivers who have severe anxiety and severe depression is higher if they care for patients with non-malignant diseases.
7. During the care process, anxiety increases statistical significantly in case of persons who care for cancer patients.
8. Two months after the patient's death, the level of anxiety and depression is statistically significantly reduced but the level it reaches remains at a risk value that can influence psychiatric pathology in the future.
9. The caregiver'burden is directly correlated with their anxiety and their depression.
10. The burden of care is statistically significantly correlated with the subjective perception of the quality of life of the main caregiver of the patient with palliative needs.
11. The primary caregivers of patients with non-oncological diseases have statistically significantly affected vitality, limiting the role due to emotional problems and perceptions of one's own health.
12. The primary caregivers of oncological patients have a statistically significant impairment in terms of limiting the role through physical and emotional problems.
13. Social life is significantly affected for all primary carers regardless of the pathology of the person they care for.
14. The number of daily administrations in a non-parental way has been significantly correlated statically with the burden of the main caregiver.
15. No statistically significant correlation was identified between the burden of care and the cost of medication
16. The complexity of the treatment plan is the same regardless of the patient's pathology, oncological or non-oncological diseases.

17. The burden of the primary caregiver is statistically significantly correlated with the complexity of the treatment plan, but not with the route of medication administration.
18. The first three classes of drugs used in the treatment of nononcological patients are: cardiovascular, neurological and psychiatric medication.
19. The first three classes of drugs used in the treatment of oncological patients are: gastroenterological, cardiovascular and psychiatric medication.
20. Non-opioid analgesic medication is used just as frequently regardless of the patient's pathology.
21. Weak and strong opioids are used statistically significantly to control the pain of cancer patients and very rarely in patients with non-oncological diseases.

Originality of the study

The hereby study represents the first original research paper that evaluates the primary caregiver burden in Romania as its correlation with psycho-emotional disorders, with life quality and treatment plan from drug procurement to the administration.

In this study the burden of caregiving represents ethiological factor for anxiety and depression and it affects the quality of life of the primary caregiver of the patients with palliative needs.

Non-oncological patients under palliative care are different from oncological patients as caretime and grade of care's dependence. Number of care needs differ from one case to another. This research paper is the first that compare the burden of care depending on the oncological and non-oncological pathology of the cared-for person.

At the moment when palliative care is initiated, the burden of care's person who is handling of a non-oncological patient is significantly higher than in the case of the person who takes care of an oncological patient. It's forms a flat due to the primary caregiver burnout by almost for times longer duration of care and the late access in a specialized service. In case of caring for an oncological patient the care process runs faster such that after three months it ends up growing as much as in non-oncological patient case. The burden of caring for a non - oncological patient runs over a longer period of time, fact that will determine an adaptation of the caregiver to this situation and also higher burnout grade in the late moment when accesses a palliative healthcare services.

The burden aspects are different. Physical exhaustion is obvious in the case of non-oncological patient care, but the pshycho-emotional disorders are present in the case of oncological patient care.

The burden of care it directly correlates both with anxiety and depression of the primary caregiver regardless of the pathology of the person cared for. Two months after the end of the care process, the involved persons have a return of the depression and anxiety score, but it remains a risk of decompensation in the future.

The subjective perception of the primary caregiver quality life is negatively correlated with the experienced burden in the care process. Quality of life aspects are influenced regardless of the pathology of the patient cared-for, but with some differences. Primary caregiver has a low energy with the perception of the worsening of one's own state of health due to emotional issues if he take care of a non-oncological patient.

In the case of caring for an oncological patient he experiments a limitation of his role due to both of physical and emotional issues. Social life is affected regardless of pathology by restricting socialization, marginalization of the primary caregiver.

The complexity of the treatment plan is the same and it doesn't depend on the oncological or

non-oncological pathology, the care needs being almost the same for a patient in palliative care. Non-parenteral daily administration number which is fully managed by the primary caregiver represents an element that correlates positively with the burden of care.