Health-related quality of life, disease burden and cognition in meningioma patients and their informal caregivers

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Primary Objectives The main objective of this project is to evaluate the long-term disease burden in meningioma patients. More specifically, we will evaluate: 1) the level of cognitive functioning and HRQoL in meningioma patients at least 5 years...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON43957

Source
ToetsingOnline

Brief title
Disease burden in meningioma patients and their informal caregivers

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
meningioma, Primary brain tumor

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Er is geen financiering voor dit onderzoek;de onderzoeken bij patiënten en naasten zullen worden uitgevoerd door een

daarin getrainde geneeskundestudent;die hiervoor geen financiële vergoeding krijgt

Intervention

Keyword: Cognition, Disease burden, Health-related quality of life, Meningioma

Outcome measures

Primary outcome

1) Neurocognitive functioning. This will be assessed with a comprehensive test battery consisting of the following validated neuropsychological tests:

- The Rey Auditory Verbal Learning Test
- The Concept Shifting Test
- The Memory Comparison Test
- Categoric Word Fluency Test
- The Digit-Symbol Substitution Test
- The Stroop Colour-Word Test

2) Health-related quality of life

- Medical OUtcomes Study (MOS) Short-Form Health Survey (SF-36) questionnaire
- European Organisation for Research and Treatment of Cancer (EORTC) QLQ-BN20 questionnaire

3) Level of work productivity

- Short Form - Health and Labor Questionnaire

4) Health resource utilization

- study-specific questionnaire

5) Caregiver burden

- Caregiver Burden Scale (CBS)

6) Anxiety and depression

- Hospital Anxiety and Depression Scale (HADS)

Secondary outcome

The following patient characteristics will be retrieved from the medical records: age, gender, tumor characteristics, Karnofsky Performance Status (KPS), neurological and cognitive functioning (if available), date of diagnosis/PA, number of seizures in the last three months, the received treatment (surgery/radiotherapy and supportive treatment) from diagnosis, and complications after treatment. A study-specific questionnaire will include the following items: level of education, current or last profession and comorbidity.

The following characteristics of informal caregivers will be assessed with a study-specific questionnaire and will include: age, gender, level of education, current or last profession, relation to the patient and comorbidity.

Study description

Background summary

Meningiomas are the most common primary brain tumors in adult patients, with an incidence of 7.44 per 100.000 patients. Although the majority of meningiomas are benign (WHO grade I), a small percentage is malignant (WHO grade II and III). The prognosis for meningioma depends on tumor characteristics (grade, size and location) and patient*s age, clinical condition and neurological status. In the absence of growth, a wait-and-scan approach is often applied to

patients with asymptomatic or minimally symptomatic meningiomas, while growing or symptomatic meningiomas are treated with surgery and/or radiotherapy. Surgery is considered the first choice of treatment, but stereotactic radiosurgery and external-beam radiotherapy are being used increasingly for meningiomas that are surgically inaccessible, recurrent or incompletely resected. The life expectancy of meningioma patients is significantly compromised, with a 20-year survival rate of 53% for WHO grade I meningiomas versus 67% in an age- and sex-specific reference group.

Although the majority of meningiomas is benign, their location in the central nervous system can cause serious morbidity. The most common symptoms at presentation are focal or generalized seizures, focal neurological deficits and cognitive decline. On the long-term (>=5 years), many patients experience neurological deficits, with the majority (67%) showing at least one neurological symptom and 27% of the patients being unable to perform normal daily activities.

With regard to cognition and health-related quality of life (HRQoL) in meningioma patients, surprisingly little rigorous studies have been performed to date. Previous studies have found that both cognition and HRQoL are impaired in untreated meningioma patients with stable lesions when compared to healthy controls. This implies that having a meningioma per se already has an impact on the patient*s cognition and HRQoL. Moreover, it is likely that treatment also has an impact on cognition and HRQoL. On the one hand, treatment may reduce the tumor mass, resulting in alleviation of neurological symptoms and improvement of cognitive functioning and HRQoL. On the other hand, treatment may damage the normal tissue surrounding the tumor, causing neurological and cognitive deficits, and subsequently impaired HRQoL. Meningioma patients treated with surgery alone have significantly impaired cognitive functioning when compared to healthy controls. However, the addition of radiotherapy to surgery did not have additional deleterious effect on cognition in these patients. Instead, the use of anti-epileptic drugs seems to attribute to neurocognitive deficits. HRQoL of most patients with WHO grade I meningioma appears to be similar to that of the general population, with 80% being satisfied with their post-treatment HRQoL and 86% reporting a pre-morbid level of functioning three years post-treatment. However, the addition of radiotherapy to surgery did result in significantly lower HRQoL.

With 5-year survival rates of 85.6% for WHO grade I tumors, 82.3% for WHO grade II tumors and 66% for WHO grade III tumors, it is worthwhile to better explore cognitive functioning and HRQoL in meningioma patients on the long-term. More specifically, the frequency and severity of impairments in cognition and HRQoL at least 5 years after primary treatment are currently unknown. It is also not known if deficits in cognitive functioning and lower HRQoL may be associated with the intensity of anti-tumor treatment (i.e., surgery/radiotherapy only once or multiple treatments throughout the disease trajectory). Moreover, the disease burden for meningioma patients may not be restricted to impaired

cognition and HRQoL, but may also be manifested in loss of work productivity due to the long-term effects of the disease or treatment and increased healthcare resource utilization.

Meningioma does not only negatively affect the patient, but may also have a profound impact on the patients* direct social environment, including family and friends. These significant others often become informal caregivers. Across different stages of the disease in cancer patients, the caregiver burden is found to be high and informal caregivers may experience considerable levels of psychological distress. Subsequently, this resulted in impaired HRQoL of significant others. So far, the disease burden in informal caregivers of meningioma patients has not been studied.
Investigating the long-term disease burden of meningioma may increase our knowledge on the beneficial and adverse effects of specific treatment strategies and may help to identify problems that might be addressed by specific interventions, intending to improve outcome for these patients and their informal caregivers.

Therefore, the aim of the current study is to examine the long-term disease burden in both meningioma patients and their informal caregivers.

Study objective

Primary Objectives
The main objective of this project is to evaluate the long-term disease burden in meningioma patients. More specifically, we will evaluate:
1) the level of cognitive functioning and HRQoL in meningioma patients at least 5 years after primary treatment and compare these scores to those of their informal caregivers (as controls, for cognition only) and matched controls from the general population (for HRQoL);
2) how cognitive functioning and HRQoL are related to treatment frequency (i.e., meningioma patients treated only once or multiple times throughout the disease trajectory); and
3) the level of work productivity and the health resource utilization of meningioma patients and their informal caregivers in the year prior to inclusion.

Secondary Objectives
(1) As distress (i.e., anxiety and depression) can influence both cognitive functioning and HRQoL, the experienced level of distress in meningioma patients will be evaluated as a secondary objective.
(2) Furthermore, we aim to determine disease burden over time, in those meningioma patients previously assessed one year post-operatively.
(3) Finally, we will determine the long-term burden (HRQoL, anxiety, depression, caregiver burden) experienced by informal caregivers of meningioma patients, as well as their level of work productivity and their health resource

utilization.

Study design

This will be a multicenter cross-sectional study. Meningioma patients and their informal caregivers who meet the inclusion and exclusion criteria, and who are willing to participate, will be asked to participate. Meningioma patients will be asked to complete several questionnaires (including HRQoL, productivity loss with work and health resource utilization) and to undergo a neuropsychological assessment once. In addition, the informal caregivers of the meningioma patients are asked to complete several questionnaires once, including HRQoL, caregiver burden and anxiety and depression, and also to undergo a neuropsychological assessment once.

To determine disease burden over time (see secondary research objectives), we will particularly invite meningioma patients who participated in a previous cross-sectional study; patients in this study were evaluated for neurocognitive functioning and HRQoL one year after surgery. We will compare the newly obtained data with this existing data to determine if neurocognitive functioning and HRQoL changed over time.

Several groups of meningioma patients will be included at >5 years after diagnosis: patients who did not undergo treatment, patiente who underwent only one form of treatment (surgery/radiotherapy),and patients who underwent multiple anti-tumor treatments (additional surgery/radiotherapy). Scores of patients on neurocognitive tests will be compared to scores of their informal caregivers, which serve as a control group. Scores on HRQoL questionnaire will be compared with a reference population matched for age and gender, which is readily available. Here, we choose not to use the informal caregivers as controls due to the likely influence of the patients* diagnosis and treatment on HRQoL of informal caregivers.

To assess the extent of response bias, we will perform a non-response analysis. To do so, baseline characteristics of patients willing to participate and those not willing to participate (but who are eligible for participation) will be compared. Demographic and clinical information will be collected from the medical charts, including age, gender, level of education, current or last profession, comorbidity and disease related characteristics.

Study burden and risks

There are no direct benefits for patients and their informal caregivers participating in this study. Nevertheless, their paticipation will contribute to a better understanding of the long-term disease burden of a meningioma. Subsequently, this information may be used to improve the care for this patient population.

On the other hand, participation in this study has possible risks for the patients and their informal caregivers. Patients and their informal caregivers are confronted with all sorts of problems they have (e.g. with cognition, health-related quality of life, work, etc.), which may pose a little psychological burden on them. Moreover, it will cost the patients and their informal caregivers time to complete the questionnaires and to undergo the neuropsychological testing, although this is expected not to be substantial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
(1) Adult patients, must be over 18 years old;
(2) Patients with a histologically confirmed or suspected intracranial meningioma;

(3) The end of the primary anti-tumor treatment was at least 5 years prior to inclusion. ;Every participant will be asked if there is an informal caregiver available to participate as well. They are:
(1) Adults; over 18 years old;
(2) The spouse, family member, or close friend of the patient;
(3) They provide the majority of emotional and physical support to the patient.

Exclusion criteria

Patients:
(1) Currently receiving anti-tumor treatment;
(2) Having received whole-brain radiation for a disease other than a confirmed or suspected intracranial meningioma;
(3) Diagnosed with neurofibromatosis type 2;
(4) Diagnosed with a neurodegenerative disease influencing their cognitive abilities;
(5) Incompetent and not having a legal representative to provide consent to study participation on their behalf;
(6) Insufficient understanding of the Dutch language;
(7) Not signed informed consent.;Informal caregivers:
(1) Insufficient understanding of the Dutch language;
(2) Diagnosed with a neurodegenerative disease influencing their cognitive abilities;
(3) The patient does not sign informed consent;
(4) No signed informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2016

Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	18-04-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL54866.029.15