

Why visually impaired older adults often do not receive mental health services: the patient's perspective

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Abstract

Purpose Older adults with a visual impairment are particularly vulnerable for increased depression and anxiety symptoms; however, they tend to underutilise mental health services. The present study aims to characterise the perceived need for and barriers to use mental health services in visually impaired older adults based on Andersen's behavioural model.

Methods A cross-sectional study in 871 visually impaired older adults (mean age 73 years) from outpatient low vision rehabilitation services was conducted. A multinomial logistic regression analysis was performed to assess potential-related factors to perceived need for mental health services, measured with the Perceived Need for Care Questionnaire (PNCQ).

Results About 35 % of the population had subthreshold depression and/or anxiety, and 13 % had a mood and/or anxiety disorder according to the DSM-IV. Almost 34 % of the participants with an actual disorder did not receive mental health services, even though 57 % perceived to be in need of these services. Participants who had more severe

depression and/or anxiety, comorbid depression and anxiety, no history of major depressive disorder, a lower perceived health status and a younger age were more likely to be in need of mental health services. Barriers to receive these services were lack of knowledge and self-reliance.

Conclusions Findings support the implementation of counselling methods, instead of medication, and patient empowerment to reduce an unmet need of mental health services in visually impaired older adults, for which extensive research is warranted.

Keywords Low vision · Depression · Anxiety · Mental health services · Perceived needs

Abbreviations

PNCQ	Perceived Need for Care Questionnaire
CES-D	Centre for Epidemiologic Studies Depression
HADS-A	Hospital Anxiety and Depression Scale-Anxiety subscale
MINI	Mini International Neuropsychiatric Interview
EQ5D	EuroQol-5 Dimensions

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Introduction

Impaired vision is one of the leading causes of disability in older people. An estimated 285 million people worldwide are visually impaired, of which 65 % is 50 years or older. This number will only increase because of demographic ageing in developing countries [1]. Vision loss has a direct effect on physical dysfunction and limitations in daily life activities and may lead to a lower life satisfaction and increased depressive and anxiety symptoms [2–5].

About one-third of visually impaired older adults experiences clinically significant symptoms of depression and/or anxiety (called subthreshold depression and/or anxiety) [2–9], which is at least twice as high as the prevalence in the general older population [10–12]. Subthreshold depression might progress to major depressive disorder [13, 14] and has the potential to become a long-term condition in visually impaired older adults [15–17]. About 7 % of older adults with a visual impairment has a major depressive disorder [2, 18], which is substantially higher than the community prevalence in older adults (mean prevalence 1.8 %) [10]. Depression and anxiety have been considered serious medical conditions as they may aggravate disability caused by the visual impairment [19], increase vulnerability for health decline [20] and decrease quality of life [21], which in turn may negatively influence low vision rehabilitation outcomes [22].

However, depression and anxiety often remain undetected and untreated in visually impaired older adults [23–25]. This may be due to the difficulty of distinguishing depression from normal grief associated with loss of vision and the infrequent use of screening tools [25]. The focus of both professionals and patients is often on physical symptoms and less on psychological issues [23–25]. Moreover, patients often do not perceive a need for professional mental health services [26–32]. Sturrock et al. [32] found that 37 % of adults with a visual impairment did not desire psychological support and only 20 % reported ever receiving this. A systematic review in the general adult population showed that 16–51 % of adults with subthreshold depression and/or anxiety did not perceive any need for mental health services [26].

Andersen's behavioural model is one of the most widely used frameworks to determine health care use [27]. The model distinguishes three factors that determine utilisation and perceived need for mental health services from the patient's perspective: (1) predisposing factors, (2) enabling factors and (3) clinical need factors. Predisposing factors represent biological imperatives for the need of health services, such as age, gender and education. Enabling factors are necessary for utilisation to actually take place, such as income level and insurance coverage. Clinical need

factors represent illness variables, such as perceived health status and severity of depression and anxiety [27].

Studies have shown that the predisposing factors female gender and younger age and the clinical need factor comorbidity of depression and anxiety were positively associated with perceived need for treatment in the general adult population and that pessimism, self-reliance, lack of knowledge, non-response and stigma proved to be barriers for using mental health services [26]. In visually impaired older adults, higher levels of depression and poorer coping concerning vision loss were positively associated with a desire for mental health services [32].

However, insight into the perceived need for and barriers to health care utilisation in older adults with a visual impairment is limited. Therefore, extensive research, based on a widely used framework as Andersen's behavioural model, is warranted. This might offer important indications to direct an inherently vulnerable population to the services they need, which can improve their autonomy, participation, psychological wellbeing and quality of life. In this study, (1) the utilisation of mental health services, (2) the perceived need for mental health services, (3) factors associated with perceived need for mental health services and (4) barriers for not receiving (sufficient) mental health services were investigated in visually impaired older adults (aged ≥ 50 years).

Methods

Design and sample

Cross-sectional data were collected from September 2012 to July 2013 as part of a randomised controlled trial on the (cost-)effectiveness of a stepped care programme to prevent the development of mood and anxiety disorders in visually impaired older adults (trial registration: <http://www.trialregister.nl>, identifier: NTR3296) [33]. In total, 3,000 patients of 50 years and older from outpatient low vision rehabilitation services in the Netherlands and Flanders (the Dutch speaking part of Belgium) were addressed to take part in the study. Eligibility criteria for low vision rehabilitation are described in the Dutch guideline 'vision disorders, rehabilitation and referral' [34] and follow the World Health Organisation (WHO) criteria. All patients in low vision rehabilitation have a decimal visual acuity of ≤ 0.3 and/or a visual field of $\leq 30^\circ$ around the central point of fixation and/or an evident help request for which therapeutic options in regular ophthalmic practice are not sufficient. Of the 3,000 addressed patients, 914 gave written consent to participate and were screened for eligibility based on structured telephone interviews (response rate of 30.5 %). Eligible participants had sufficient knowledge of

the Dutch language and no severely impaired cognitive functioning, as measured with the Six-item screener [35]. Participants who did not answer at least one question on the Perceived Need for Care Questionnaire (PNCQ) (the main outcome measure) were also excluded ($n = 37$). Therefore, data of 871 participants were finally available for the present study.

Measurements

Perceived need for mental health services

In order to measure perceived need for mental health services and the utilisation of these services, the PNCQ was used. This questionnaire was designed for the Australian National Survey of Mental Health and Well-being and showed acceptable reliability, validity and feasibility [36]. In the present study, the translated Dutch version of the PNCQ from the Netherlands Study of Depression and Anxiety (NESDA) was used [37]. Descriptive information of five different types of mental health services was distinguished: (1) information about mental illnesses and treatment possibilities; (2) practical support, e.g. vision-specific tools or domestic help; (3) skills training; (4) counselling/therapy; and (5) medication [36]. In concurrence with a comparable study in a Dutch general older population, a sixth category: ‘referral to a mental health services specialist’ was added [31]. Respondents were asked whether they received some type of care in the past 6 months, whether this type of care was needed and whether it was sufficient. Additionally, participants with an unmet need for mental health services could indicate one of the nine possible barriers for not receiving (sufficient) mental health services: (1) self-reliance; (2) pessimism; (3) financial situation; (4) lack of knowledge; (5) stigma; (6) non-response; (7) being on a waiting list; (8) already in treatment; or (9) alternative help was provided [36].

Covariates

Based on Andersen’s behavioural model, the following covariates were selected: *predisposing factors*: gender, age, nationality, years of education and living situation, *enabling factors*: income level (almost all participants had insurance coverage so this was not included as a covariate) and *clinical need factors*: perceived health status, severity of depression and/or anxiety, comorbid depression and anxiety, history of major depressive disorder, visual acuity, main cause of vision loss, time of onset and somatic comorbidity.

Decimal visual acuity was retrieved from patient files at the rehabilitation centres and supplemented with the answers that visually impaired older adults themselves

gave. These were converted into LogMAR visual acuity in the best eye, with a visual acuity of 0.00–0.29 indicating normal visual acuity, 0.30–0.51 mild vision loss and 0.52–2.00 indicating low vision or blindness.

Somatic comorbidity was assessed based on: osteoarthritis and rheumatoid arthritis; asthma or chronic obstructive pulmonary disease; cancer; peripheral arterial disease; diabetes mellitus; cardiac disease; cerebrovascular accident or stroke; and other chronic health disorders.

Symptoms of depression and anxiety were measured with the widely used Centre for Epidemiologic Studies Depression scale (CES-D). The CES-D consists of 20 items with four response categories, with scores ranging from 0 to 60, with a score of ≥ 16 indicating subthreshold depression and/or anxiety [38–40]. It is considered a valid and reliable instrument in Dutch older adult populations for measuring depressive and anxiety symptomatology [38–40]. However, the criterion validity of the CES-D was considerably better for depression than for anxiety [40]. Hence, to optimise sensitivity and specificity, the anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A) was used in the present study for measuring anxiety. HADS-A is considered a valid and reliable instrument to use in Dutch older adult populations [41–43]. It has seven items with four response categories and scores ranging from 0 to 21, with a score of ≥ 8 indicating subthreshold anxiety [41–43].

To distinguish participants with a DSM-IV mood disorder (major depressive or dysthymic disorder) and/or anxiety disorder (panic disorder, agoraphobia, social phobia and/or general anxiety disorder), the Dutch version of the Mini International Neuropsychiatric Interview (MINI) was used. The MINI has proven to be a valid instrument to use in medical telephone screening [44, 45] and an appropriate standardised tool to diagnose DSM-IV mood and anxiety disorders in Dutch clinical practice [44].

Perceived health status was measured using the Dutch EuroQol-5 Dimensions (EQ5D), which is considered a valid and reliable instrument [46]. The EQ5D consists of five dimensions of functional impairment: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Scores range from 0 (which corresponds to death) to 1 (which corresponds to full health) [46].

Statistical analysis

Data analysis was performed using SPSS 20. Descriptive analyses demonstrated clinical and demographic characteristics of the population. The variables education and comorbidity were recoded into the number of years having received education and the number of chronic somatic disorders that participants reported as being treated for by a physician. Living situation (dependent or independent) and cause of vision loss (macular degeneration or other) were

dichotomised. The variable severity of depression and/or anxiety was divided into three groups: (1) no depression and anxiety (CES-D score of <16 and HADS-A score of <8); (2) subthreshold depression and/or anxiety (CES-D score of ≥ 16 and/or HADS-A score of ≥ 8); and (3) having a mood and/or anxiety disorder (based on the MINI). To measure the perceived health status, the scores of the EQ5D were calculated according to validated Dutch standard values [46]. Similar to a study in a general adult population [30], the outcome variable perceived need for mental health services was categorised into three groups; (1) no need of mental health services; (2) in need of mental health services, which indicated that a person's need was not or only partially met; and (3) met need of mental health services, which indicated that the need for mental health services was fully met.

To determine potential factors related to perceived need for mental health services, a multinomial logistic regression analysis was performed, with the 'in need' group as reference group. The assumption of absence of multicollinearity between the different covariates was tested. The best fitting model was determined based on a backwards stepwise procedure.

Results

Patient characteristics, service utilisation and perceived need

No significant difference was found between responders and non-responders in gender; however, non-responders were significantly older than responders (mean difference = 4.6 years, $p < 0.001$). The most common reasons for not participating in the study were: (1) it was too great a burden to participate and (2) patients were physically or mentally not able to participate. Participants were mainly female and had an average age of 73.3 years, and almost, all of them lived independently (Table 1). The most frequent causes of vision loss were macular degeneration (46 %), glaucoma (16 %) and cataract (14 %), and the mean time of onset of the visual impairment was 16 years ago. About 35 % suffered from subthreshold depression and/or anxiety, and 13 % had an actual disorder according to the DSM-IV. About 57 % of the study population did not receive any form of mental health services. Practical support was the most frequently received form of help, followed by medication. Mental health services were mostly offered by a social worker, followed by a psychologist or psychiatrist.

Table 2 shows that about 53 % of the respondents with subthreshold depression and/or anxiety and 34 % of the respondents with a mood and/or anxiety disorder did not

Table 1 Characteristics of the study population ($N = 871$)

Patient characteristics	
Female gender [N (%)]	527 (60.5 %)
Age (years), range [50–98] [mean (SD)]	73.32 (12.08)
Nationality [N (%)]	
Dutch	766 (87.9 %)
Belgian/other	105 (12.1 %)
Education (years), range [0–16] [mean (SD)] ^a	10.23 (3.53)
Income level [N (%)] ^b	
Usually enough money	426 (48.9 %)
Just enough money	363 (41.7 %)
Not enough money	65 (7.5 %)
Living situation [N (%)]	
Independent	818 (93.9 %)
Care home/other	53 (6.1 %)
Cause of vision loss [N (%)] ^c	
Macular degeneration	399 (45.8 %)
Glaucoma	137 (15.7 %)
Cataract	122 (14.0 %)
Cerebral haemorrhage	49 (5.6 %)
Diabetic retinopathy	33 (3.8 %)
Other	131 (15.0 %)
Time of onset (years), range [0–88] [mean(SD)] ^d	16.00 (19.71)
Visual acuity best eye (LogMAR) [N (%)] ^e	
Normal visual acuity	106 (12.2 %)
Mild vision loss	159 (18.3 %)
Low vision or blindness	550 (63.1 %)
Somatic comorbidity, range [0–7] [mean (SD)] ^f	1.04 (1.14)
No symptoms of depression/anxiety [N (%)] ^g	515 (59.1 %)
Subthreshold depression and/or anxiety [N (%)] ^g	308 (35.4 %)
Mood and/or anxiety disorder [N (%)]	117 (13.4 %)
Mood and anxiety disorder [N (%)]	33 (3.8 %)
Mood disorder [N (%)]	
Depression	57 (6.5 %)
Dysthymic disorder	18 (2.1 %)
Total	75 (8.6 %)
Anxiety disorder [N (%)]	
Panic disorder	14 (1.6 %)
Agoraphobia	42 (4.8 %)
Social phobia	26 (3.0 %)
General anxiety disorder	28 (3.2 %)
Total	75 (8.6 %)
History of major depressive disorder [N (%)]	127 (14.6 %)
Types of mental health services received [N (%)]	
Information about illness and treatment	92 (10.6 %)
Practical support	228 (26.2 %)
Skills training	21 (2.4 %)
Counselling/therapy	96 (11.0 %)
Medication	102 (11.7 %)
Referral to specialist	38 (4.4 %)

Table 1 continued

Patient characteristics	
No mental health services received	499 (57.3 %)
Clinicians/care providers [<i>N</i> (%)]	
Social worker	178 (20.4 %)
Psychologist or psychiatrist	87 (10.0 %)
Outpatient or hospital treatment	7 (0.8 %)
Other	77 (8.8 %)

Missing observations (*N*): ^a62; ^b17; ^c6; ^d15; ^e56; ^f3; ^g46

receive any form of mental health services in the past 6 months, indicating that as the severity of depression and anxiety increased, participants more often received mental health services. In addition, as symptoms of depression and anxiety increased, participants more often expressed a need for professional mental health services; 57 % of the participants with a mood and/or anxiety disorder reported to be in need of mental health services compared to 29 % of the participants with subthreshold symptoms.

Participants who were in need of mental health services expressed 394 different requests for help; often, they reported more than one type of request (Table 3). Participants were most often in need of practical support; skills training; information about mental illnesses and treatment possibilities and counselling/therapy. A need for medication and referral to a mental health services specialist were least often reported. Participants expressed different reasons for not receiving treatment (Table 4). Lack of knowledge was mentioned most often, followed by self-reliance, being on a waiting list, non-response and already being under treatment.

Potential factors related to perceived need for mental health services

No plausible multicollinearity was found. All the predisposing, enabling and clinical need factors were

Table 3 Requests for help

Types of requests	<i>N</i>	%
Practical support	89	22.6
Skills training	87	22.1
Information	85	21.6
Counselling/therapy	79	20.1
Referral to mental health services specialist	40	10.2
Medication	14	3.6
Total	394	100

Table 4 Perceived reasons for not receiving mental health services

Cited reason	<i>N</i>	%
Lack of knowledge ('I didn't know where to get (extra help')	119	31.5
Self-reliance ('I rather solve it myself')	61	16.1
Waiting list ('I am on a waiting list')	52	13.8
Non-response ('I asked for it but didn't get it')	43	11.4
Already in treatment ('I am already in treatment')	39	10.3
Pessimism ('I thought this would not help')	21	5.6
Stigma ('I was afraid to ask for help; what would others think?')	16	4.2
Financial situation ('I did not have the money')	14	3.7
Alternative help ('I already received help in another form/capacity')	13	3.4
Total	378	100

included in a multinomial logistic regression model (Table 5; full model). After conducting the backward stepwise procedure, the *predisposing factor*: age and the *clinical need factors*: severity of depression and/or anxiety, comorbid depression and anxiety, history of major depressive disorder and perceived health status, proved to be significantly related to perceived need for mental health services (Table 5; end model). The final model explained 18.9 % (Cox and Snell R^2) to 21.8 %

Table 2 Severity of depression and/or anxiety in relation to received and perceived need for mental health services

	Received mental health services			Need for mental health services			
	No care	Some form of care	Total	No need	Met need	In need	Total
Depression/anxiety ^a							
No symptoms	319 (63.7 %)	182 (36.3 %)	501 (100 %)	329 (65.7 %)	116 (23.2 %)	56 (11.2 %)	501 (100 %)
Subthreshold symptoms	112 (53.3 %)	98 (46.6 %)	210 (100 %)	91 (43.3 %)	58 (27.6 %)	61 (29.0 %)	210 (100 %)
Disorder	39 (34.2 %)	75 (65.8 %)	114 (100 %)	31 (27.2 %)	18 (14.5 %)	65 (57.0 %)	114 (100 %)
Total	470 (57.0 %)	355 (43.0 %)	825 (100 %)	451 (54.7 %)	192 (23.3 %)	182 (22.1 %)	825 (100 %)

Missing observations (*N*): ^a46

(Nagelkerke R^2) of the variance in perceived need for mental health services.

The strongest factor related to perceived need for mental health services was severity of depression and/or anxiety. Compared to respondents with a mood and/or anxiety disorder, respondents with subthreshold depression and/or anxiety and no symptoms were significantly more likely to have no need for mental health services than to be in need of these services (OR = 1.92 and 6.07, respectively) and were significantly more likely to have their needs met than to be in need of mental health services (OR = 2.60 and 5.72, respectively). These results show that participants were more often in need of mental health services as the severity of depression and/or anxiety increased. In addition, participants with comorbid depression and anxiety were significantly more likely to be in need of mental health services than to have no needs for these services (OR = 4.26). Participants with higher perceived health status were more likely to have no need for mental health services than to be in need of care (OR = 3.94), and patients with a history of major depressive disorder were more likely to have met needs than to be in need of mental health services (OR = 0.51). The model, furthermore, shows that as age increased, participants were more likely to express no need and met needs for mental health services, than to be in need of care (OR = 1.03 and 1.02, respectively), indicating that participants with a younger age were more likely to be in need of mental health services.

Discussion

This study confirms that depression and anxiety are a major health problem in visually impaired older adults. About 35 % of the population suffered from clinically significant depression and/or anxiety symptoms, and 13 % had an actual mood and/or anxiety disorder. This is substantially higher than the prevalence found in general older populations [5, 7, 10–12]. However, they often do not receive any form of mental health services, even though they had all been in contact with professionals from low vision rehabilitation centres and in most cases with their general practitioner and ophthalmologist. This is underlined by other studies in older populations [26, 27, 31, 32] and is a matter of great concern, because of the detrimental impact of depression and anxiety in this inherently vulnerable population [19–21].

More than half of the participants with a mood and/or anxiety disorder reported to be in need of mental health services; a finding consistent with other studies [26, 31, 32, 47]. Participants with more severe depression and/or anxiety, comorbid depression and anxiety, and a lower

perceived health status more frequently expressed a need for professional mental health services. These *clinical need factors* were also found in other studies [26, 28, 31, 32, 47]. Furthermore, the results showed that people with a history of major depressive disorder were less often in need of mental health services as their needs were more often fully met, indicating that these people already know where to find the required services.

In addition, the *predisposing factor* age was significantly related to perceived need for mental health services. Older participants were more likely to express no need for mental health services than younger participants; a finding also reported by others [26, 32, 47–50]. Possible explanations for this might be that older adults will manage with gained life experience or more often indicate the preference to solve problems themselves. The latter might be due to the time-period in which these participants grew up. Values and standards were different: mental health problems were not recognised as medical conditions, and it was not common to openly talk about it. This may have led to present difficulty of acknowledging a need for mental health services. Differences between participants in ‘working ages’ (50–65 years old) and ‘non-working ages’ (≥ 65 years old), which were both included in the present study, might also have led to differences in mental health needs as studies show that these groups have different life goals and rehabilitative needs [51, 52].

The main reason for an unfulfilled need for mental health services was lack of knowledge, indicating that visually impaired older adults do not have sufficient knowledge about mental illnesses and treatment possibilities. In studies in the general older population, this reason was mentioned less often [26, 31]. A lack of knowledge might be due to the focus of both patients and professionals on physical symptoms rather than psychological issues and the difficulty of distinguishing depression and anxiety from normal grief associated with vision loss [23–25]. To stimulate the screening process in becoming a routine part of patient care professionals may be stimulated to use brief, validated screening tools to be able to detect symptoms of depression and anxiety. A short version of the patient health questionnaire (PHQ), which can also be used by non-mental health staff, might be suited for this purpose [53, 54].

The second most frequently mentioned reason for not receiving (sufficient) mental health services was self-reliance, indicating that a proportion of the study population rather solves problems themselves. In at least two studies in the general population, this reason was mentioned most often [31, 49]. Professionals can stimulate these patients by promoting patient empowerment, in which patients are offered guidance in solving their problems corresponding to their own need of self-reliance, whilst under the

professional supervision of health care providers. Patient empowerment is already being applied in many different fields of health care [55]. Guided self-help, a structured treatment method based on cognitive behavioural therapy (CBT) with limited professional guidance, is one of the possibilities [33, 56, 57].

However, it might also be possible that these responses (lack of knowledge and self-reliance) are caused by patients' difficulty of acknowledging a need for mental health services. Professionals should be aware of this possibility and stimulate patients in overcoming this difficulty.

The present study showed that the need for counselling methods (information, practical support, therapy and skills training) was much higher than the need for medication, which is in line with the systematic review of Prins et al. [26]. This indicates that professionals should focus on offering counselling methods instead of medication to satisfy an unmet need for mental health services in this population. Some research on counselling methods has been conducted, indicating that, e.g. self-management programmes [58, 59] and problem solving treatment [60] can be effective in reducing depression and anxiety in visually impaired older adults. However, extensive research is warranted.

Strengths and limitations

The present study is the first to investigate the utilisation of, the perceived need for and barriers to receive mental health services in a visually impaired older population, based on the widely used framework of Andersen's behavioural model. The outcomes might not only be used for research, but also for clinical practice as it offers important indications to direct visually impaired older adults to the services they need to improve their psychological well-being. Validated questionnaires were used to analyse perceived need for mental health services and potential-related factors, which allows for comparison with other studies. In addition, a large number of patients were included, which increases the reliability and generalisability of the results.

However, the results should be interpreted with caution. First, this study was based on a cross-sectional design giving no indication of the sequence of events. Therefore, it is impossible to infer causality between the investigated covariates and the outcome measure. Second, study participants may differ from individuals in the general visually impaired population. They may for instance be relatively healthier as they were able to take part in the interviews and were not cognitively impaired. In addition, they might have had higher needs for and better access to health care as they were all patients of low vision rehabilitation

services. Third, non-responders were significantly older than responders, and older patients proved to be less often in need of mental health services. This may have resulted in an overestimation of the number of participants found to be in need of mental health services.

Further studies are needed to investigate longitudinal data to determine predictors of perceived need for mental health services in this population, in which non-clinical participants might be included and additional covariates (such as other psychiatric disorders) might be investigated.

Conclusion

Visually impaired older adults who suffer from depression and/or anxiety often do not receive mental health services. However, many of them do perceive a need for it. Participants who were most inclined to be in need of mental health services had more severe symptoms of depression and/or anxiety, comorbid depression and anxiety, no history of major depressive disorder, a lower perceived health status and a younger age. The main reasons for an unfulfilled need for mental health services were lack of knowledge and self-reliance. Findings support the implementation of counselling methods, instead of medication, and patient empowerment to reduce an unmet need for professional mental health services in this population. Extensive research on (cost-)effective counselling interventions is warranted.

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Conflict of interests The authors declare that they have no competing interests.

Ethical standard The present study has been approved by the Medical Ethics Committee of the VU University Medical Centre (Amsterdam, the Netherlands) and the University Hospital Leuven (Belgium) and has, therefore, been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients gave written consent to participate in the present study.

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