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A European survey on the detection and management of iron overload in transfusion-dependent patients with MDS

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Running title: Survey on treatment of iron overload in MDS

Abstract

To better understand the detection and management of iron overload in transfusion-dependent patients with myelodysplastic syndromes (MDS), a 15-minute web- or paper-based survey was conducted among 338 European physicians from 27 countries. Respondents had a mean of 18 years' clinical experience. 46% and 27% of physicians noted that detecting and treating iron overload were either 'very important' or 'important', respectively. The main reason for not actively exploring iron overload was related to poor patient prognosis, while the main reasons for not initiating iron chelation therapy were poor patient prognosis and older patient age. 37% and 31% of physicians believed that treating iron overload in these patients was 'very important' or 'important', respectively. 90% of physicians prescribed iron chelation therapy, and 38% of transfusion-dependent patients received iron chelation therapy. The key reasons for not initiating iron chelation therapy related to poor patient prognosis (72%), patient age ≥ 85 years (50%) and comorbidities (34%). The views of these experienced MDS physicians reflect available international MDS treatment guidelines.

Key words:

MIDIS, Myelodysplastic syndromes, Transfusions, Iron overload, Iron chelation, Survey

Introduction

1
2 Red blood cell (RBC) transfusions are a common therapy to treat symptomatic anemia that
3 affects most patients with myelodysplastic syndromes (MDS) [1]. Several retrospective
4 studies have shown that patients who become RBC transfusion dependent have a significantly
5 shorter overall survival than those who are not dependent on transfusions [2,3]. This
6 decreased survival may in part be due to patients accumulating excess iron and/or to
7 intrinsically more severe bone marrow disease than in non-dependent patients. International
8 Prognostic Scoring System (IPSS) Low- and Intermediate-1 (Int-1)-risk patients, who may
9 have prolonged survival, receive blood transfusions for many years and may be exposed to a
10 greater risk of iron overload, leading to progressive dysfunction in organs such as the liver,
11 heart and endocrine glands [2,4].
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22 Guidelines from Spain, [5] The Italian Society of Hematology, [6] The UK MDS Guidelines
23 Group, [7] The National Comprehensive Cancer Network in the USA [8] and The MDS
24 Foundation [4] all recommend the use of iron chelation therapy in patients with Low- or Int-
25 1-risk MDS who have received more than 20 to 50 transfusions. In Europe, these
26 recommendations, although not based on controlled clinical trials demonstrating superiority
27 of iron chelation versus observation alone, have an impact on the perceptions and
28 prescriptions of iron chelation therapy in patients with MDS. There is currently some
29 controversy regarding the use of iron chelation therapy in these patients, particularly because
30 they have a median age of 70 years, and many patients with a poor prognosis may not survive
31 long enough to develop the clinical consequences of iron overload [9-11]. There is some
32 argument, however, that even patients with higher-risk MDS may also benefit from iron
33 chelation therapy through improved outcome of allogeneic stem cell transplantation, possible
34 decreases in infection, and, although controversial, delayed leukemic transformation in some
35 cases [6,12].
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49 In order to understand what physicians treating transfusion-dependent patients with MDS in
50 Europe believe to be the reasons for their willingness or reservations towards detecting and
51 managing iron overload, a survey of European physicians has been conducted. The MDS
52 Iron-overload Detection Insight Survey (MIDIS) was conducted by the MDS Foundation and
53 the European School of Haematology (ESH) in partnership with Novartis Oncology. The
54 results of the survey are presented here.
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2 **Design and Methods**
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4 *Inclusion/exclusion criteria*
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6 To participate in the study, respondents had to be physicians from a European country, either
7 fully qualified, in training or completing their internship, and seeing at least one transfusion-
8 dependent patient with MDS in an average 6-month period.
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13 MIDIS was initiated at the 2008 meeting of the American Society of Hematology and was
14 also distributed at other international conferences via e-mails, letters and flyers, as well as
15 links to the survey hosted on the MDS Foundation and ESH websites.
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21 *Study questionnaire*
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23 MIDIS was a quantitative survey that comprised up to 33 structured questions that could be
24 completed either on paper or online in approximately 15 minutes. The questions were
25 reviewed by a study steering committee, comprising the authors and external experts, prior to
26 being included in the survey. The questions related to: profiling and demographics of the
27 respondents (qualification status, primary specialty, work setting, number of transfusion-
28 dependent patients with MDS seen, involvement in MDS); detection of iron overload
29 (frequency of serum ferritin testing, influence of serum ferritin tests on treatment decisions;
30 importance of detecting iron overload, potential reasons for and reservations against
31 detection); and treatment of iron overload with chelation therapy (importance of treatment,
32 use of iron chelation therapy, markers for therapy initiation, number of patients who receive
33 iron chelation therapy, potential reasons for and reservations against iron chelation therapy).
34 Questions relating to detection and treatment of iron overload were answered using a scale
35 from 1 (indicating not important at all) to 7 (very important). Questions relating to barriers
36 and triggers for detecting and treating iron overload were also answered using a scale from 1
37 (indicating not a barrier or trigger at all) to 7 (a strong barrier or trigger).
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Analysis

Collection and analysis of the MIDIS results were undertaken by the HealthCare Division of GfK SE. The results for both respondents' background, and barriers and triggers toward detection and treatment of iron overload, were analyzed quantitatively.

Results

Respondent demographics

A total of 338 physicians from 27 European countries participated in the survey (Table 1). Their profile shows that they were experienced clinicians specializing mostly in hematology (Table 2). A total of 88% were involved in diagnosing patients with MDS, 87% initiated treatment for MDS, and the same proportion was involved in the maintenance of treatment for MDS. The survey was completed by the respondents themselves.

Table 1 Countries represented in the survey

Country	Responses	Country	Responses
Austria	8	Macedonia	6
Belgium	22	Malta	1
Bulgaria	4	Netherlands	2
Croatia	4	Norway	2
Czech Republic	19	Poland	11
Denmark	5	Portugal	9
Estonia	4	Romania	6
Finland	1	Serbia	1
France	43	Slovakia	19
Germany	20	Spain	45
Greece	16	Sweden	4
Hungary	3	Switzerland	7
Italy	39	UK	36
Lithuania	1		
Total number of responses		338	

Table 2 Respondent characteristics

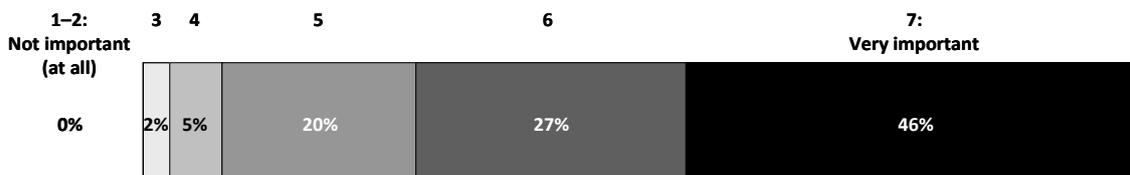
Characteristic	n = 338
Mean age, years	44
Male : female, n (%)	183 (54) : 155 (46)
Primary specialty, n (%)	
Hematologist	312 (92)
Oncologist	8 (2)
General practitioner	4 (1)
Transfusionist	2 (0.6)
Cytogeneticist	1 (0.3)
Other physician	11 (3)
Qualification, n (%)	
Fully qualified	293 (87)
In training or completing internship	45 (13)
Work place, n (%)	
Teaching hospital	199 (59)
General hospital	95 (28)
Office-based, cancer center, private hospital or other	44 (13)
Experience as a physician, mean number of years*	18
<16 years' experience, n (%)	159 (47)
≥16 years' experience, n (%)	177 (52)
Mean number of patients with MDS seen per month, n	18
As a proportion of total patients seen, %	12
Mean number of transfusion-dependent patients with MDS seen over a 6-month period, n	19

*Two (1%) respondents did not answer this question

Detection of iron overload

On a scale from 1 (not important at all) to 7 (very important), the majority of the respondents believed that detection of iron overload in transfusion-dependent patients with MDS was 'very important' (score 7; 46% of respondents) or 'important' (score 6; 27%; Fig. 1). The mean score for the subjective importance of detecting iron overload in transfusion-dependent patients with MDS was 6.1.

Fig. 1 Subjective importance of detection of iron overload

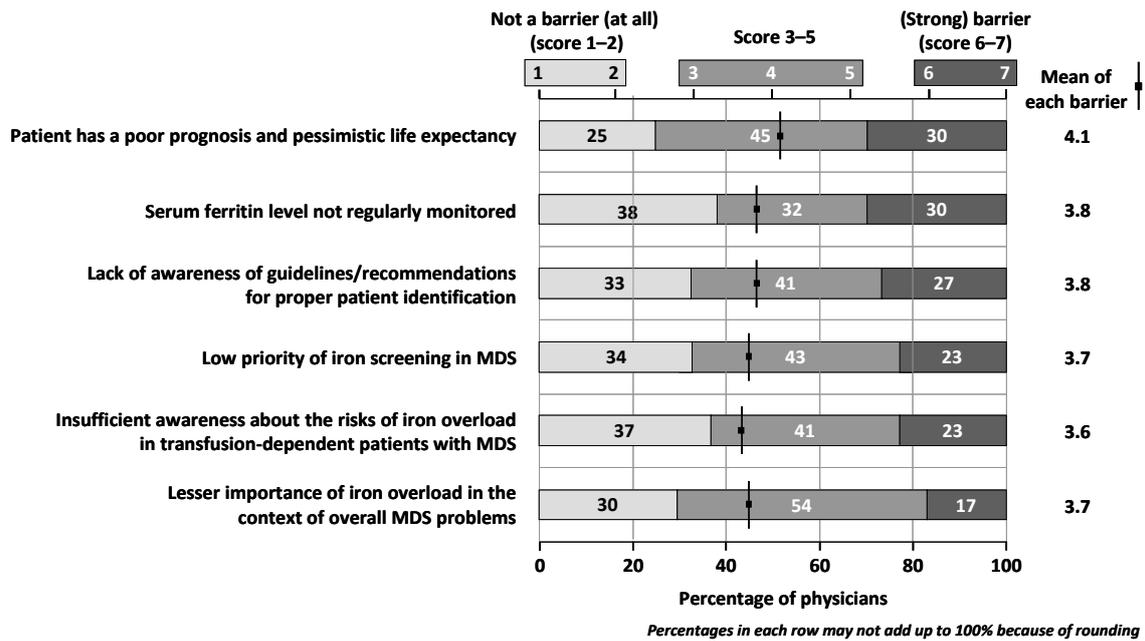


On a similar 1–7 scale, most respondents believed that it was ‘very likely’ (score 7; 40%) or ‘likely’ (score 6; 25%) that iron overload would be detected at their institution (mean score = 5.8). Approximately half of the respondents (53%) said that they monitored serum ferritin levels in their transfusion-dependent patients every 3 months, with 26% responding that the frequency of serum ferritin monitoring depended on the rate of transfusions that the patient was receiving. Respondents said that in 46% of cases, the results of serum ferritin monitoring ‘always’ influenced their decisions on how they treated their patients, and ‘sometimes’ influenced this in 47% of cases.

The factors that positively influenced detection of iron overload included: patients having received >20 RBC units (relevant trigger in 76% of respondents); introduction of serum ferritin as a standard test (76%); and awareness of the potential risks of frequent transfusions (75%). On a scale from 1 (not an aid at all) to 7 (a strong aid), the mean scores for these factors were 6.1, 6.1 and 6.0, respectively.

The most important reasons for not detecting iron overload were poor patient prognosis, irregular serum ferritin monitoring, as well as lack of awareness about guidelines and risks of iron overload (Fig. 2). Other reasons included a low priority for iron-overload screening, and perceptions about the importance of iron overload in MDS.

Fig. 2 The most important reservations about the detection of iron overload

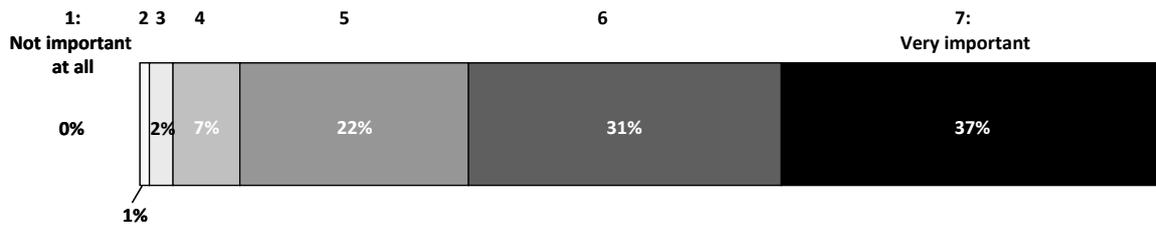


Respondents' opinions were polarized about whether or not regularly monitoring serum ferritin levels was a reason for not detecting iron overload. While 30% said that this 'strongly prevented' or 'prevented' them from detecting iron overload, a similar proportion of respondents (38%) believed that this 'did not', or 'did not at all', prevent them from detecting iron overload (Fig. 2).

Treatment of iron overload with iron chelation therapy

On a scale from 1 (not important at all) to 7 (very important), respondents said that they believed that treating iron overload in transfusion-dependent patients with MDS was 'very important' (score 7; 37% of the respondents) or 'important' (score 6; 31%) the mean score was 5.9 (Fig. 3).

Fig. 3 Subjective importance of treating iron overload



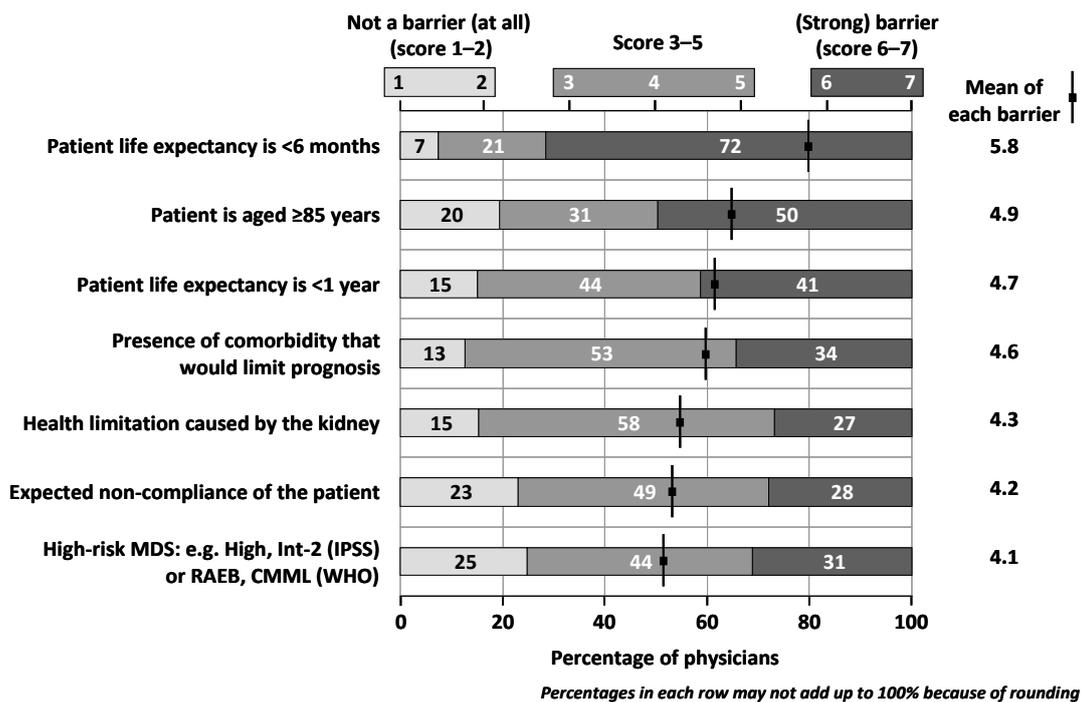
The survey showed that 90% of respondents prescribed iron chelation therapy to their transfusion-dependent patients with MDS. Nonetheless, not all of these patients received iron chelation therapy; out of a mean of 34 transfusion-dependent patients with MDS seen in each of the respondents' practices or institutions in an average 6-month period, 13 (38%) received iron chelation therapy.

The factor that most led respondents to initiate iron chelation therapy was patient age of 55–64 years (relevant trigger in 77% of respondents). On a scale from 1 (does not lead the respondent to initiate iron chelation therapy at all) to 7 (strongly leads to initiation of iron chelation therapy), the mean score for this factor was 5.9. Other factors that most led respondents to initiate iron chelation therapy included: serum ferritin levels >1000 ng/mL (76%; mean score 6.0); candidacy for allogeneic stem cell transplantation (76%; mean score 6.0); need to prevent organ dysfunction (74%; mean score 6.0); ≥ 2 RBC units transfused per month (71%; mean score 5.9); lifetime transfusions of >20 RBC units (68%; mean score 5.8); and convenience of oral iron chelation therapy (67%; mean score 5.8).

The majority of respondents who prescribe iron chelation therapy (92%) felt that a patient's serum ferritin reaching a specific level was a marker at which to initiate iron chelation therapy. The mean serum ferritin level at which these respondents initiated iron chelation therapy was 1130 ng/mL. More than half of the respondents who prescribe iron chelation therapy (56%) said that reaching a certain number of blood units transfused was also a marker (mean of 21 units). Other markers for initiating iron chelation therapy included: patients having received a particular number of transfusions (mean of 18 transfusions; 41% of respondents who prescribe iron chelation therapy); and the rate of increase of a patient's serum ferritin level (33% of respondents who prescribe iron chelation therapy).

The strongest reasons for not initiating iron chelation therapy were mostly related to poor patient prognosis and patient age ≥ 85 years (Fig. 4). There were polarized opinions regarding the importance of some of the reasons for not initiating iron chelation therapy. For example, while 31% of respondents replied that a high-risk MDS classification was a strong barrier to initiating iron chelation therapy, 25% thought that this did not represent a significant barrier. Similarly, while 28% said that expected non-compliance was a strong barrier to initiating iron chelation therapy, 23% thought this was a weak barrier. Some of the reasons for not initiating iron chelation therapy specifically related to the age of the patients being treated. Older patient age was less of a reason to initiate iron chelation therapy, and more of a reason not to, than younger patient age.

Fig. 4 The most important reservations about initiating iron chelation therapy. Abbreviations: *RAEB* refractory anemia with excess blasts; *CMML* chronic myelomonocytic leukemia; *WHO* World Health Organization



Discussion

This survey was undertaken to better understand what physicians perceive to be the key reasons for investigating iron overload and managing iron overload when treating transfusion-dependent patients with MDS, and the reasons that they do not. The respondents who took part in MIDIS were from multiple European countries, and the majority were

1 experienced physicians who appeared to have a keen interest in the MDS therapy area. Over a
2 quarter had more than 25 years' experience working as physicians and the majority were
3 actively involved in the diagnosis and treatment of patients with MDS. The survey has the
4 known limitations of optional surveys; i.e., it was performed on invitation at conferences or
5 through e-mail alerts and weblinks. Therefore, the survey may have been biased towards
6 respondents with an interest in MDS, and who may have had a greater understanding of the
7 management of iron overload than the general population of hematologists. Furthermore,
8 MIDIS is not a representative sample of the hematologists from each country, and the number
9 of respondents from each country does not accurately reflect the proportion of that country's
10 hematologists in Europe.
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20 Nonetheless, the results of the survey provide a valuable insight into the practices and beliefs
21 of European physicians treating transfusion-dependent patients with MDS. MIDIS showed
22 that approximately 70% of the respondents believed that detecting and treating iron overload
23 were important in patients with MDS. A total of 76% of physicians felt that a serum ferritin
24 level >1000 ng/mL was a relevant trigger to initiate iron chelation therapy. Over 50% of the
25 respondents monitored serum ferritin levels quarterly as a surrogate marker for iron overload
26 in their patients and, overall, 38% of transfusion-dependent patients with MDS were actively
27 being treated for iron overload with iron chelation therapy. In Europe the prevalence of MDS
28 patients with Low/Int-1-risk MDS (according to the IPSS) is reported to be approximately
29 70% [2], and 39–50% of those patients are transfusion dependent [13]. Therefore,
30 approximately one-third of patients will be transfusion dependent and may be candidates for
31 iron chelation therapy, according to published guidelines. The 38% response by the survey
32 respondents reflects their active iron chelation treatment strategy. This is confirmed by a
33 recent study showing that 41% of eligible patients with lower-risk MDS received iron
34 chelation therapy in clinical practice [14]. In all, the views expressed in the survey are in line
35 with a number of international guidelines that recommend that serum ferritin levels should be
36 assessed 3–4 times per year in transfusion-dependent patients with MDS, and that iron
37 chelation therapy should be initiated when their serum ferritin level reaches 1000 ng/mL,
38 depending on the transfusion rate [4,15-17]. Interestingly, fewer than a quarter of the
39 respondents considered concerns about potential reductions in patient quality of life, the cost
40 of iron chelation therapy and possible side effects of therapy as strong reasons for not
41 initiating treatment. Only 23%, 19% and 11% of respondents, respectively, reported these as
42 barriers or strong barriers to initiating treatment. Furthermore, the issue of potentially reduced
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2 quality of life was polarized; the proportion of respondents who considered this to be a
3 barrier was similar to the proportion who did not (23% and 26%, respectively).
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5 Participating physicians were asked whether considering iron overload to be a lesser problem
6 in patients with MDS was a barrier to detecting iron overload. While 17% thought this was a
7 barrier or strong barrier, 30% were strongly opposed to that view. This reflects the need for
8 evidence-based data regarding the role of iron chelation in MDS. Serum ferritin is a well-
9 known acute-phase reactant that might overestimate the iron load in the presence of other
10 diseases, in particular infectious episodes [18]. More accurate measurements of iron overload
11 include liver and heart magnetic resonance imaging; however, these are time consuming and
12 not available at many centers. This may be one reason why one third of MIDIS respondents
13 said that they believed that irregular monitoring of serum ferritin levels was a strong barrier
14 to detecting iron overload, while 38% thought that this did not prevent detection.
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25 The survey respondents were reluctant to administer iron chelation therapy to patients aged
26 ≥ 85 years. It is difficult to assess how transfusion dependence affects the overall survival of
27 this elderly patient population with Low- or Int-1-risk MDS. Nonetheless, it is interesting to
28 note that the proportion of physicians opting against iron chelation therapy for this population
29 was higher than that of physicians opting against treatment for patients with a life expectancy
30 of less than one year (Figure 4). Instead, patient age of 55–64 years was a strong reason for
31 initiating iron chelation therapy.
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40 In summary, this European survey has demonstrated that physicians believe that iron
41 overload is a relevant clinical issue in transfusion-dependent patients with MDS that is
42 worthy of investigation and treatment. Concerns over age and patient prognosis are key
43 factors in the treatment decisions taken by physicians. An ongoing, randomized Phase III trial
44 in patients with Low- and Int-1-risk MDS on iron overload in MDS will help to clarify the
45 role of iron chelation therapy in this patient population.
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Authors' contribution

AG and PF drafted the manuscript. SI analysed the data. AG, DJ, SLdP, SI and PF contributed to the study design, data interpretation, and reviewed and provided their comments on this manuscript.

Conflict of Interest

AG reports receiving consultancy and speaker bureau fees, and is a member of the board of directors or advisory committee for Novartis Pharma AG, Amgen Inc, GlaxoSmithKline plc, Johnson & Johnson Services Inc, and Celgene Corp. DJ is employed by The European School of Haematology, which receives unrestricted educational grants from Novartis Pharma AG. SLdP is Head of Patient Advocacy of Novartis Oncology Region Europe and has equity in Novartis Pharma AG. SI is a full-time employee of GfK SE, the market research agency that was commissioned and paid by Novartis Farma SpA to collect and analyze the MIDIS survey data. PF reports receiving honoraria and research funding from Celgene Corp, F Hoffmann-La Roche Ltd, Ortho Biotech Products, Amgen Inc, Cephalon Inc, Merck & Co Inc and Novartis Pharma AG.

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Figure 1

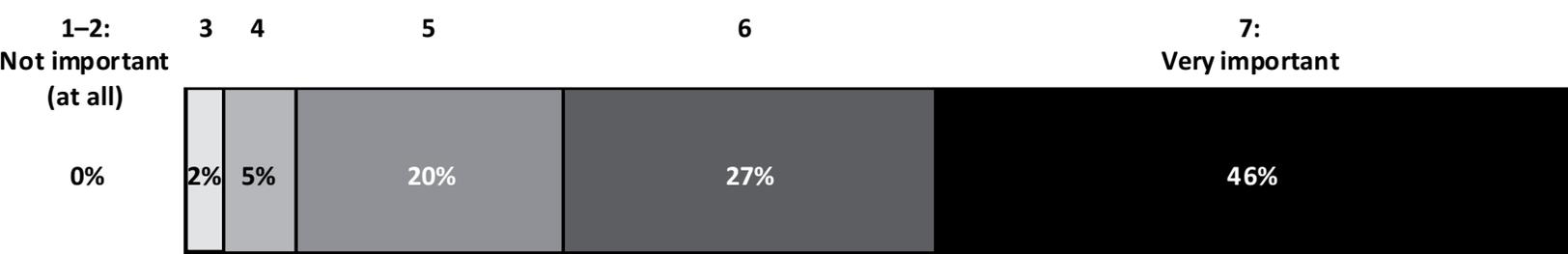


Figure 2

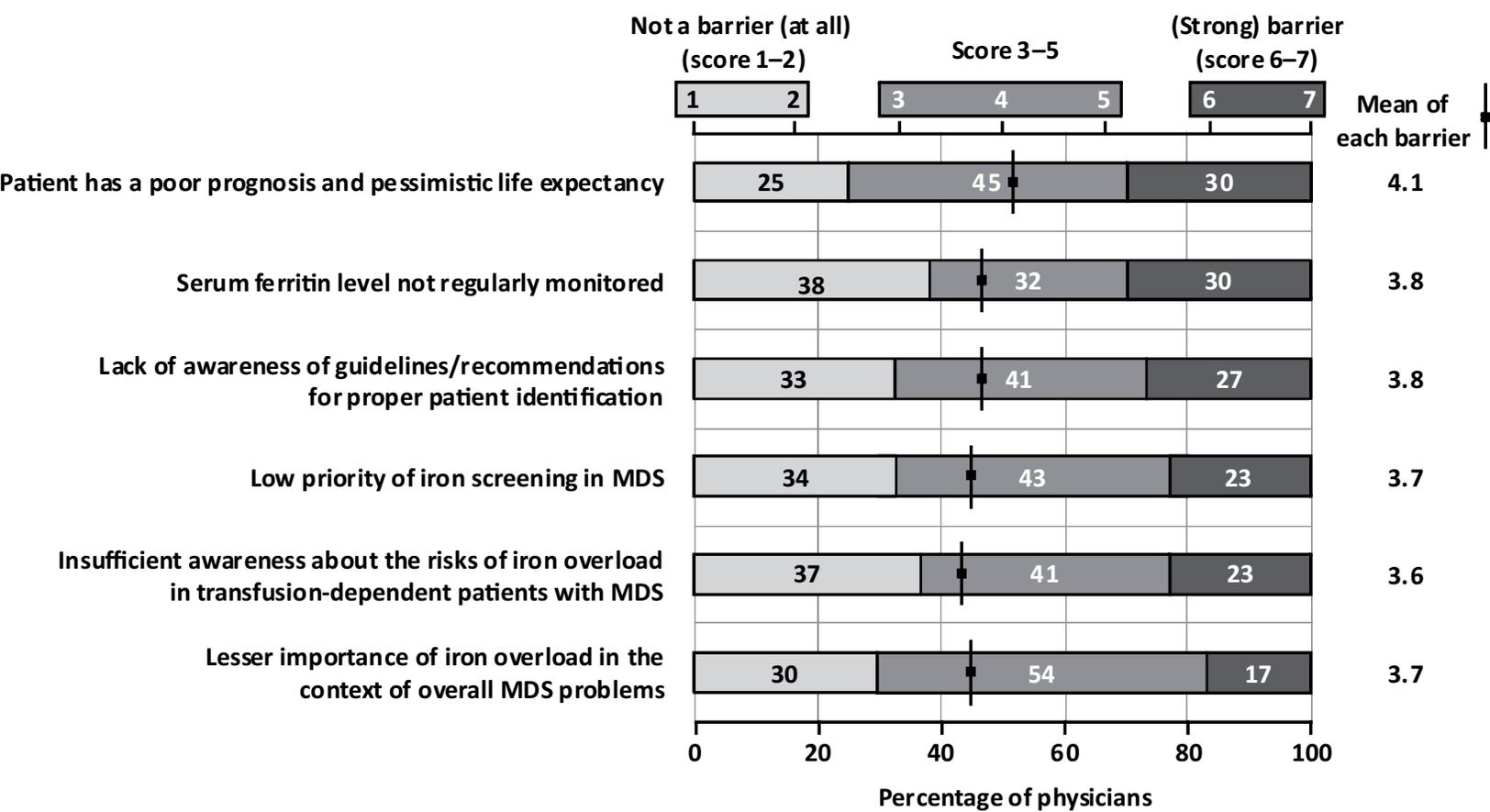


Figure 3

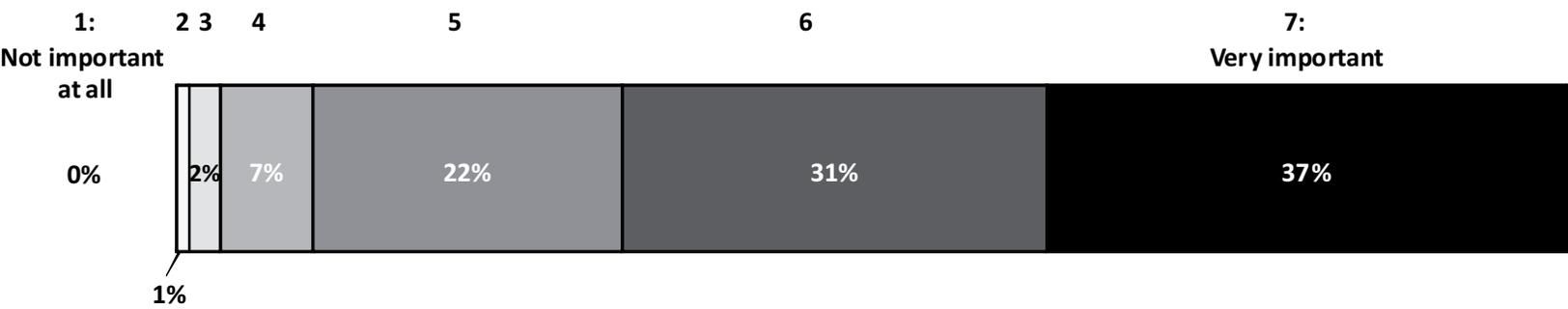


Figure 4

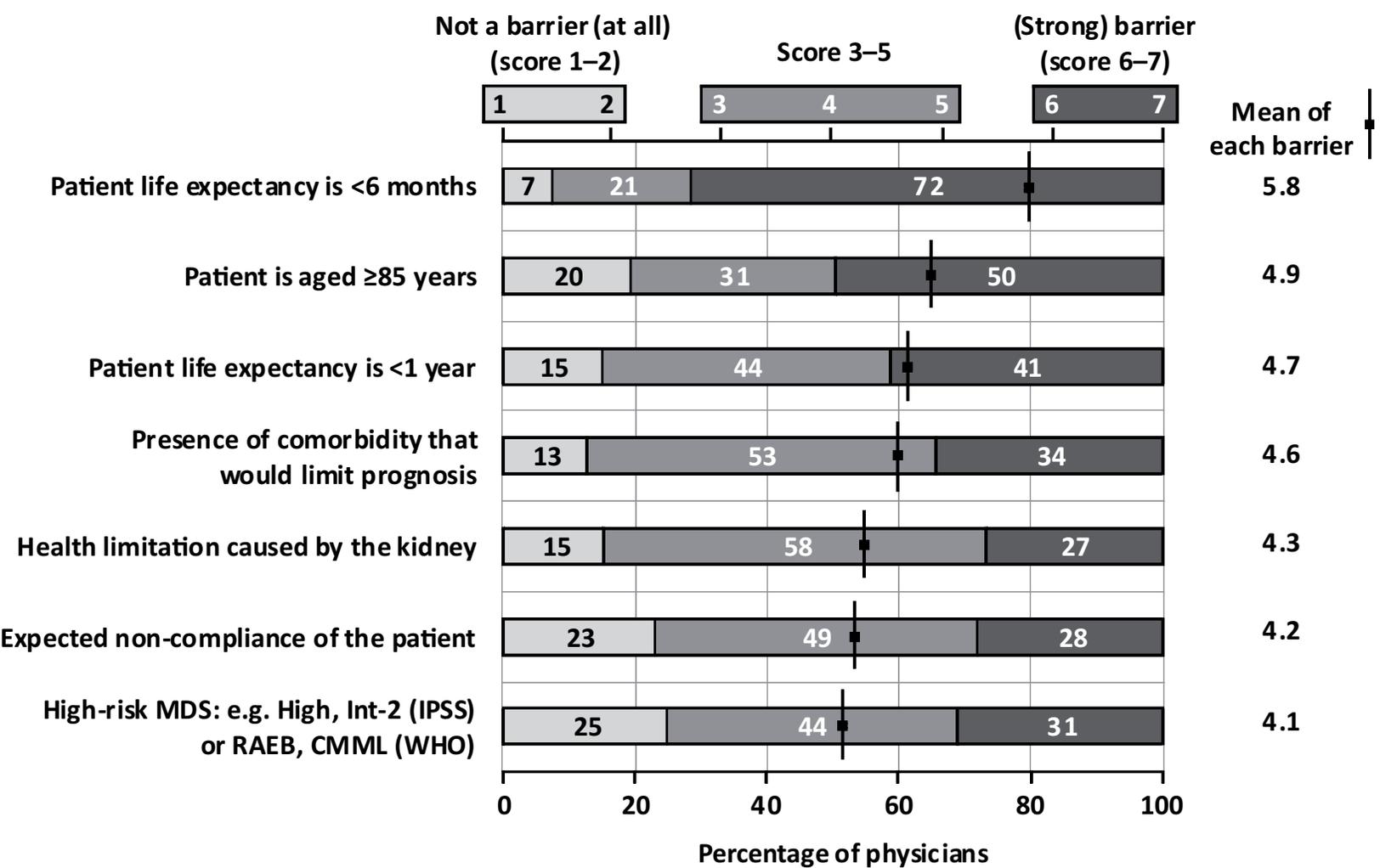


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Denmark	5	Portugal	9
Estonia	4	Romania	6
Finland	1	Serbia	1
France	43	Slovakia	19
Germany	20	Spain	45
Greece	16	Sweden	4
Hungary	3	Switzerland	7
Italy	39	UK	36
Lithuania	1		
Total number of responses			338

Table 2 Respondent characteristics

Characteristic	n = 338
Mean age, years	44
Male : female, n (%)	183 (54) : 155 (46)
Primary specialty, n (%)	
Hematologist	312 (92)
Oncologist	8 (2)
General practitioner	4 (1)
Transfusionist	2 (0.6)
Cytogeneticist	1 (0.3)
Other physician	11 (3)
Qualification, n (%)	
Fully qualified	293 (87)
In training or completing internship	45 (13)
Work place, n (%)	
Teaching hospital	199 (59)
General hospital	95 (28)
Office-based, cancer center, private hospital or other	44 (13)
Experience as a physician, mean number of years*	18
<16 years' experience, n (%)	159 (47)
≥16 years' experience, n (%)	177 (52)
Mean number of patients with MDS seen per month, n	18
As a proportion of total patients seen, %	12
Mean number of transfusion-dependent patients with MDS seen over a 6-month period, n	19

**Two (1%) respondents did not answer this question*

***Conflict of interest**

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