
High-dose melphalan and autologous haematopoietic stem cell transplantation in multiple myeloma in Norway, 2008–2020

ORIGINAL ARTICLE

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Background and aim

High-dose melphalan and autologous haematopoietic stem-cell transplantation (ASCT) is effective against multiple myeloma. The type of treatment patients receive before and after ASCT may affect time to relapse and survival. The aim of this study was to compare the treatments administered before and after ASCT at the four hospitals offering ASCT in Norway during the period 2008–2020.

Material and method

All patients who received ASCT as first-line treatment for multiple myeloma in Norway in the period 1 January 2008–31 December 2020 were included in the study. Data on demographics, disease and treatment were recorded. Patients were followed until disease progression, death or study completion.

Results

Patients who received ASCT at St Olav's University Hospital received almost exclusively bortezomib-cyclophosphamide-dexamethasone as induction therapy, while bortezomib-lenalidomide-dexamethasone dominated at the three other hospitals after 2017. Maintenance therapy was given to 27 % of patients receiving ASCT in Oslo,

compared with 2–16 % at the other centres. Median progression-free survival ranged from 29 to 38 months, and median overall survival ranged from 102 to 120 months across the centres.

Interpretation

Significant variations were observed in the treatments administered before and after ASCT, especially after 2017. National guidelines allowed for multiple treatment options, which has resulted in heterogeneous treatment practices. These different treatment approaches may have contributed to differences in progression-free and overall survival.

Main findings

The median overall survival for patients treated with high-dose melphalan and autologous haematopoietic stem cell transplantation in the period 1 January 2008–31 December 2020 was 114 months, and the median transplant-related mortality was 0.7 %.

During this period, there were regional differences within Norway in the therapy given before and after high-dose melphalan and autologous haematopoietic stem cell transplantation for multiple myeloma.

High-dose melphalan and autologous haematopoietic stem-cell transplantation (ASCT) has been used to treat multiple myeloma in Norway since the 1990s (1). In this treatment, the patient receives high-dose chemotherapy with melphalan, followed by reinfusion of the patient's previously harvested stem cells. The procedure allows the use of high-dose chemotherapy without subsequent long-term and life-threatening bone marrow failure.

ASCT are offered to patients under 70 years of age without significant comorbidities, and occasionally to patients up to 75 years. Several studies have shown that this treatment is associated with longer time to relapse or death (progression-free survival, PFS) compared with continuous therapy without ASCT, including in recent years (2, 3). The treatment has remained largely unchanged over the past 30 years, but there have been major changes in the drugs given before (induction therapy) and after (consolidation and maintenance therapy).

Studies have shown that induction therapy that achieves a deep response also results in longer progression-free survival (4, 5). With more effective combination therapies now available, there have consequently been changes in the recommended induction therapy in Norway. The main drug classes used to target malignant plasma cells in multiple myeloma include proteasome inhibitors such as bortezomib, immunomodulatory drugs such as lenalidomide, alkylating agents such as cyclophosphamide, and corticosteroids such as dexamethasone. In the period 2013–2015, bortezomib-cyclophosphamide-dexamethasone was the recommended induction therapy in Norway (6–8). From 2016, bortezomib-lenalidomide-dexamethasone and bortezomib-thalidomide-dexamethasone were placed on an equal footing with bortezomib-cyclophosphamide-dexamethasone in

the national clinical guidelines under the Norwegian action programme for malignant haematological diseases (9). Bortezomib-thalidomide-dexamethasone, however, is seldom used in Norway due to a high incidence of severe neuropathy.

In the mid-2010s, several studies demonstrated the benefit of administering treatment with these drug classes after ASCT (10–12). Consolidation therapy is a short course of combination treatment using the same or different drugs as those administered before ASCT. Maintenance therapy is low-dose treatment after ASCT, administered over several years, usually until disease progression or intolerance due to side effects.

ASCT in Norway are centralised to four hospitals: Oslo University Hospital, Haukeland University Hospital, St Olav's University Hospital and North Norway University Hospital. These centres are responsible for patients within their respective regional health authorities. In this article, we refer to the centres as Oslo, Bergen, Trondheim and Tromsø. Induction therapy, consolidation therapy and maintenance therapy are administered at local hospitals with haematology expertise and in accordance with the national clinical guidelines under the Norwegian action programme for malignant haematological diseases.

The main aim of this study is to describe differences in treatment across the regional health authorities, both in terms of the choice of induction therapy and whether consolidation and maintenance therapy were administered. We also aimed to examine transplant-related mortality following ASCT and whether progression-free and overall survival differed between the centres. The Norwegian Registry of Lymphoid Malignancies contains data on induction therapy by regional health authority from 2020, but does not include information on consolidation or maintenance therapy. Mortality following ASCT, progression-free survival and overall survival are also not reported in the registry.

Material and method

Patients

This retrospective study included all patients who received ASCT in Norway for multiple myeloma in the period 1 January 2008–31 December 2020. All patients were over 18 years of age and received the treatment as first-line therapy.

Patient lists were obtained from the four centres. Data on age, sex, type of multiple myeloma, diagnostic criteria, treatment, time to relapse and survival were collected from the electronic medical records at each centre.

We also recorded prognostic markers associated with reduced survival, including whether the patient had stage III disease according to the International Staging System (ISS) (13) and high-risk genetic abnormalities identified by fluorescent in situ hybridisation (FISH), namely t(4;14), t(14;16), and/or del(17 p) (14).

Treatment

We recorded the type of induction therapy used. If a patient switched induction therapy, classification was based on the original regimen so that the combinations were assessed according to the intended treatment plan. Consolidation therapy was recorded if the patient received a time-limited course (four cycles or fewer) of combination therapy

with multiple drugs. Maintenance therapy was recorded if the patient received a single agent active against myeloma after ASCT, intended for long-term use (i.e. at least one year).

A separate analysis was performed on the proportion of patients receiving consolidation and maintenance therapy from 2017 onwards, as substantial changes in treatment practices were expected from that year due to a new study on maintenance therapy (12) and new national guidelines in 2018 (15).

Transplant-related mortality and survival

Transplant-related mortality was defined as death within 100 days of ASCT.

Progression-free survival was defined as the time from the start of induction therapy to disease progression or death regardless of cause, whichever occurred first. Overall survival was defined as the time from the start of induction therapy to death regardless of cause.

Patients were censored at the end of the study on 31 March 2022, or earlier if they emigrated from Norway ($n = 5$), or if, at their last contact with the centre, we were unable to obtain their medical records from the local hospital ($n = 7$).

Statistics

Descriptive statistics were used to summarise patient characteristics, treatment and transplant-related mortality. The Kaplan-Meier estimator was used to determine median progression-free survival and median overall survival for each centre. Statistical analyses were performed using Stata (version 18.0, StataCorp).

Ethics

The study was approved by the Regional Committee for Medical and Health Research Ethics (REK) South-East (reference number 42833) and by the data protection officers at all relevant health trusts. Most patients had consented to the registration of their data in the European Bone Marrow Transplant (EBMT) Registry, which REK considered sufficient for these patients. For patients who had not consented to EBMT registration and were still living, an information letter about the study was sent, giving them the opportunity to decline participation. For deceased patients who had not consented to EBMT registration, REK granted a consent waiver.

Results

Patient characteristics

A total of 1354 patients received ASCT as first-line treatment for multiple myeloma in the period 1 January 2008–31 December 2020. Of these, 753 patients were treated in Oslo, 277 in Bergen, 205 in Trondheim and 119 in Tromsø (Table 1).

The median age at the time of treatment was 60 years (interquartile range 20 years) for the entire population and was roughly the same across the four centres. The two youngest patients were 30 years old, and the oldest was 75 (Table 1).

The proportion of men was 60 % overall, ranging from 57 % to 61 %. Bergen had a higher proportion of patients with ISS stage III (32 %) compared with the other centres (23–24 %). FISH revealed that 18 % of patients receiving ASCT in Oslo had high-risk findings, compared with 21–24 % at the other centres (Table 1).

Treatment

Changes in the induction therapy used over the entire observation period are shown in Figure 1. In 2008 and 2009, cyclophosphamide and dexamethasone were the most common induction regimen. Bortezomib–cyclophosphamide–dexamethasone gradually took over from 2010 and became the dominant induction therapy at all centres until 2016. From 2017, the differences between centres became more pronounced: patients receiving ASCT in Oslo mostly received bortezomib–lenalidomide–dexamethasone as induction therapy, while bortezomib–cyclophosphamide–dexamethasone continued to dominate for patients in Trondheim. In Tromsø, bortezomib–lenalidomide–dexamethasone also became more common, while in Bergen the pattern was more mixed.

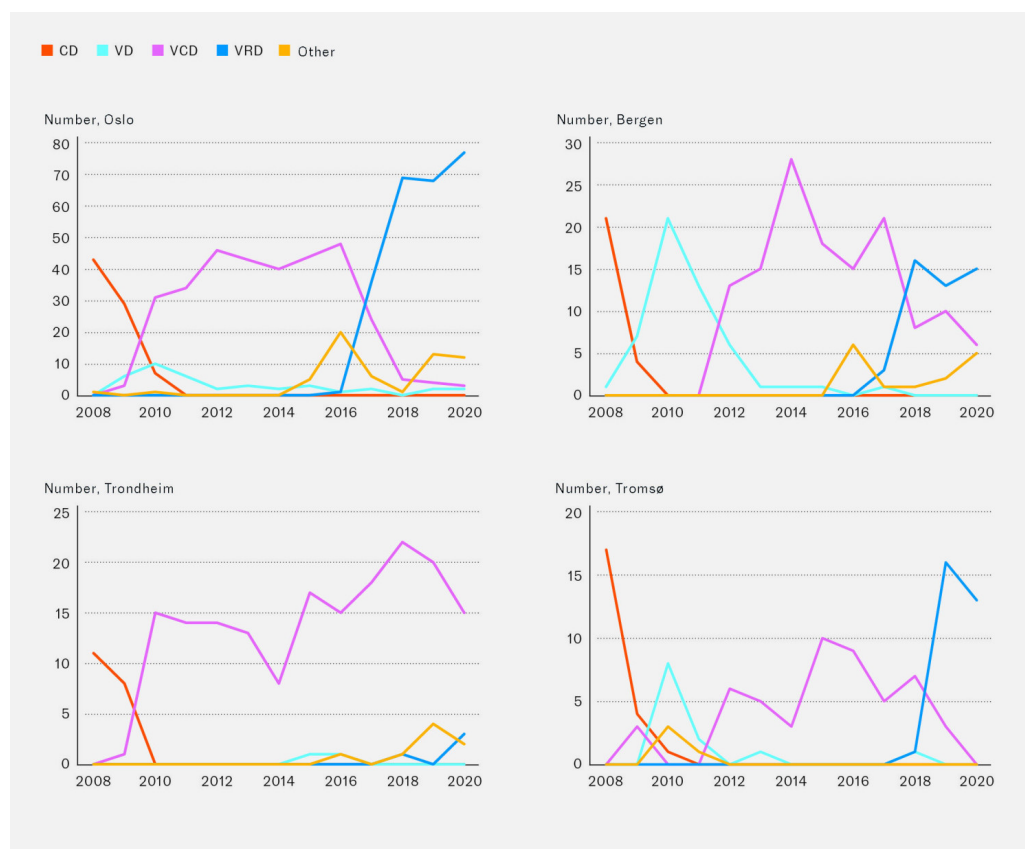


Figure 1 Number of patients receiving different induction therapies prior to ASCT at the four Norwegian treatment centres in the period 1 January 2008–31 December 2020. CD = cyclophosphamide–dexamethasone; VD = bortezomib–dexamethasone; VCD = bortezomib–cyclophosphamide–dexamethasone; VRD = bortezomib–lenalidomide–dexamethasone.

The proportion of patients receiving consolidation and maintenance therapy is shown in Table 2. Oslo had the highest proportion of patients receiving consolidation therapy (20 %) compared with 5 % in Bergen, 3 % in Trondheim and 14 % in Tromsø. Oslo also had the highest proportion of patients receiving maintenance therapy; 27 %, compared with 16 % in Bergen, 8 % in Trondheim and 2 % in Tromsø.

Among patients who received ASCT from 2017 onwards, the differences became even more pronounced. The proportion of patients receiving consolidation therapy was 40 % in Oslo, 30 % in Tromsø, 11 % in Bergen and 8 % in Trondheim. The proportion of patients receiving maintenance therapy from 2017 onwards also varied, with 50 % in Oslo, 27 % in Bergen, 13 % in Trondheim and 2 % in Tromsø.

Transplant-related mortality

Transplant-related mortality, defined as death within 100 days of treatment, was 0.7 % for the entire population, with 1 % in Oslo ($n = 5$), 1 % in Bergen ($n = 3$), 0 % in Trondheim ($n = 0$) and 1 % in Tromsø ($n = 1$).

Progression-free survival and overall survival

Median progression-free survival for the entire population was 33 months. Kaplan–Meier curves for progression-free survival at the different centres are shown in Figure 2. Patients who received ASCT in Oslo, Bergen, Trondheim and Tromsø had median progression-free survival of 38, 32, 29 and 29 months, respectively.

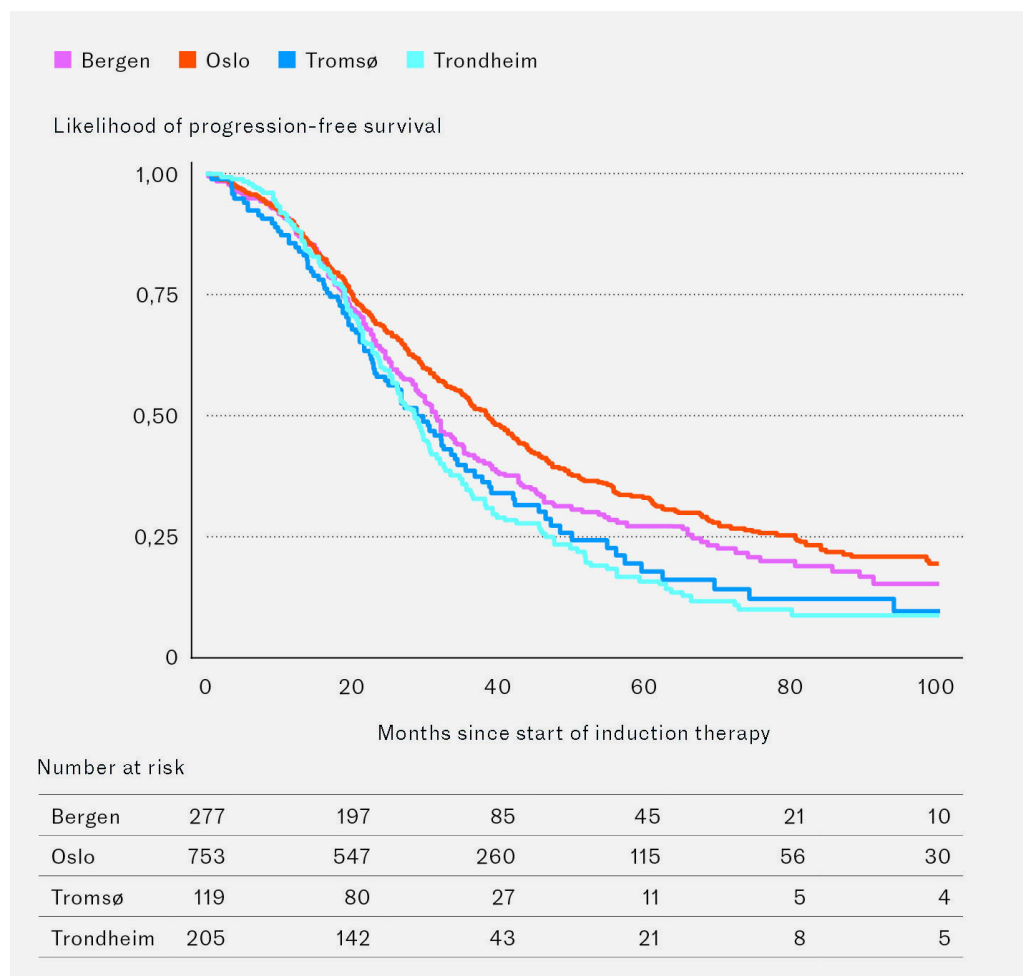


Figure 2 Progression-free survival (PFS) after ASCT at the four Norwegian treatment centres in the period 1 January 2008–31 December 2020.

Median overall survival for the entire population was 114 months. Kaplan–Meier curves for overall survival at the different centres are shown in Figure 3. Median overall survival was 120 months for patients in Oslo, 102 months in Bergen, 106 months in Trondheim and 120 months in Tromsø.

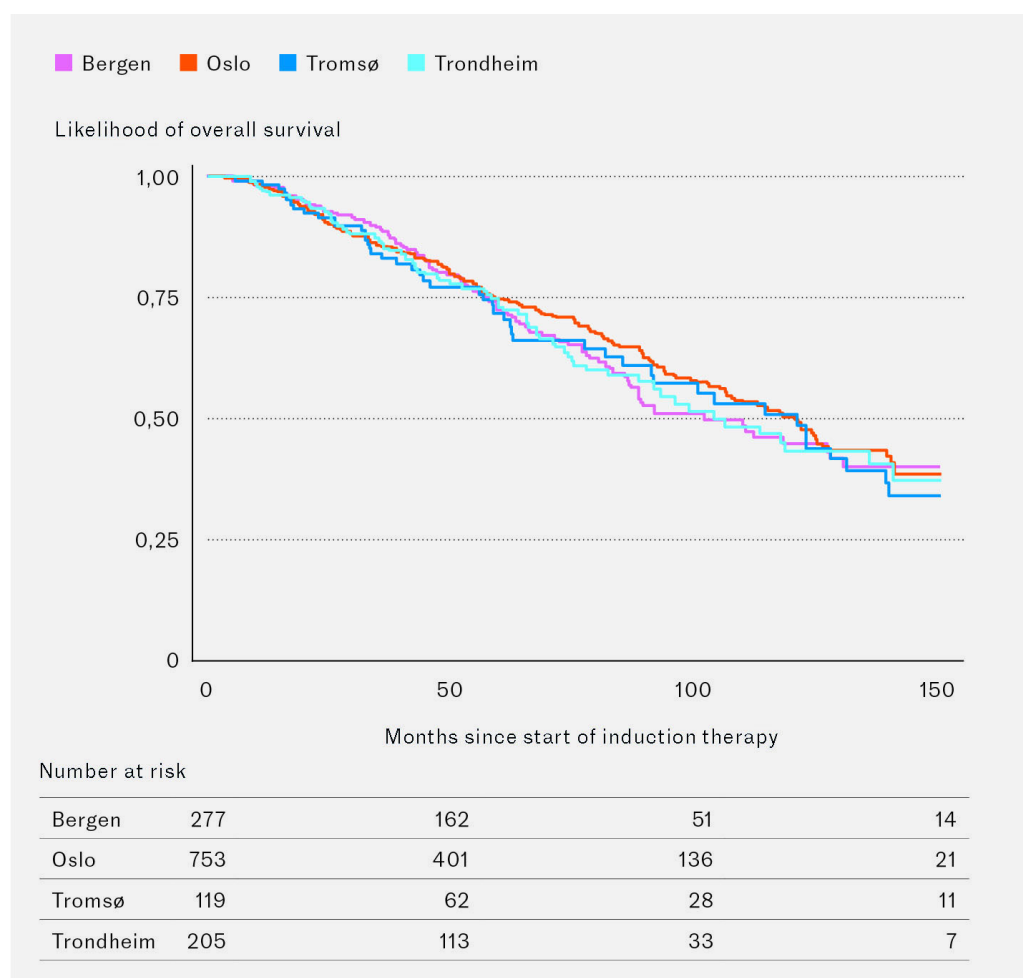


Figure 3 Overall survival after ASCT at the four Norwegian treatment centres in the period 1 January 2008–31 December 2020

Discussion

The study included all patients who received ASCT as first-line treatment for multiple myeloma in Norway during the period 2008–2020. Substantial differences were observed in treatment between the various centres, particularly from 2017 onwards. Patients in Oslo mostly received induction therapy with bortezomib–lenalidomide–dexamethasone, and the use of both consolidation and maintenance therapy was relatively common. Patients in Trondheim received almost exclusively induction therapy with bortezomib–cyclophosphamide–dexamethasone, and only a small proportion received consolidation or maintenance therapy. Bortezomib–lenalidomide–dexamethasone as induction therapy was widely used in Bergen and Tromsø, but also at these centres fewer patients received consolidation or maintenance therapy compared with Oslo.

There may be several reasons why patients in different parts of the country received different types of treatment, but the main reason is likely to be that the national clinical guidelines from 2016 placed three different induction regimens on an equal footing. Since there are no high-quality randomised trials directly comparing these induction therapies, there has been no solid basis for recommending one regimen over another, and most local hospitals have followed the advice of their regional centre. Retrospective studies have shown that induction therapy with bortezomib–

lenalidomide–dexamethasone is associated with higher response rates and longer progression-free survival compared with bortezomib–cyclophosphamide–dexamethasone (16, 17), but such studies are subject to selection bias, and caution is therefore needed when interpreting their findings.

With regard to consolidation therapy, and particularly maintenance therapy, the data from clinical trials are clearer. In several studies, maintenance therapy with lenalidomide has been associated with prolonged progression-free survival (18, 19) and overall survival (11, 20). In Norway, however, the Decision Forum for the introduction of new health technologies decided in December 2018 that this treatment should not be introduced. In the absence of reimbursement for maintenance therapy with lenalidomide, consolidation therapy was recommended in the national clinical guidelines from 2020. In December 2021, maintenance therapy with lenalidomide was reconsidered by the Decision Forum, and it was then decided to introduce the treatment from March 2022 (21).

Our data show high adherence to the national clinical guidelines under the Norwegian action programme for malignant haematological diseases. This study therefore highlights the importance of robust, up-to-date national clinical guidelines. In this area, the guidelines permitted several treatment options, which led to variations in practices between hospitals.

We found differences in median progression-free survival between hospitals, with patients in Oslo having the longest median progression-free survival at 38 months, compared with 29–32 months at the other hospitals. Differences between patient groups may have impacted on results such as these. We observed a higher proportion of patients with ISS stage III in Bergen, which is associated with a poorer prognosis. The higher proportion of patients with ISS stage III may be a result of later diagnosis than at the other hospitals, but the sample size is small and the findings should therefore be interpreted with caution. Overall, however, patient characteristics were fairly similar between the hospitals. It is therefore likely that the difference in progression-free survival is due to the use of bortezomib–lenalidomide–dexamethasone as induction therapy and the more extensive use of consolidation and maintenance therapy. A higher rate of participation in clinical trials in which consolidation and maintenance therapy form part of the treatment protocol may also be a reason for the longer progression-free survival among patients in Oslo, although this applies to only a small proportion of patients.

As might be expected, more effective treatment and treatment administered over a longer period result in longer progression-free survival, but more treatment will also lead to more outpatient visits for patients, which entails a risk of overtreatment and unnecessary use of resources. Overall survival is therefore considered the most important endpoint. Median overall survival was somewhat longer for patients in Oslo and Tromsø, which may be related to greater use of bortezomib–lenalidomide–dexamethasone as induction therapy and more frequent use of consolidation therapy. Differences in progression-free survival without corresponding differences in overall survival may be related to the possibility that patients in Trondheim, Bergen and Tromsø received treatment with lenalidomide at relapse, whereas patients in Oslo received this as part of consolidation therapy and as maintenance therapy. The 2024 annual report from the Myeloma Registry in Central Norway shows that patients in Trondheim mostly received lenalidomide as second-line treatment (22).

The median survival of 9.5 years observed in this study is encouraging and represents an improvement from the period 2005–10, when it ranged between 5.1 and 7.3 years, depending on patient age (60–65 years vs under 60) (23). It is also encouraging that transplant-related mortality was very low, which is consistent with findings from international studies (24, 25). Low transplant-related mortality suggests good patient selection and follow-up.

As this is a retrospective study, causal relationships cannot be established, and differences in progression-free survival and overall survival may be attributable to factors other than those discussed above. We lack data on comorbidities and treatment at relapse, both of which may have a substantial impact on overall survival. The survival analyses were not adjusted for differences in patient characteristics. We also lack data on the specific consolidation and maintenance therapies patients received, the indication in each case and the duration of treatment. The treatment centres' assessments of which patients should undergo ASCT may also have differed. The dataset spans a long time period, and changes in diagnostics, supportive care and treatment options may also have impacted on the results.

This review of ASCT for multiple myeloma in Norway during the period 2008–20 shows differences between hospitals in the choice of induction therapy as well as in the use of consolidation and maintenance therapy. Widespread use of bortezomib–lenalidomide–dexamethasone as induction therapy and extensive use of consolidation and maintenance therapy may explain the longer median progression-free survival observed among patients in Oslo. Transplant-related mortality was low. Overall survival has increased from the period 2005–10, and median overall survival was 9.5 years.

The article has been peer-reviewed.

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