Eje de Gestión de la Información: Mejores abstracts EBMT 2018

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Bone Marrow Transplantation
https://doi.org/10.1038/s41409-018-0323-1

ABSTRACT

The 44th Annual Meeting of the European Society for Blood and Marrow Transplantation: Data Management Group—Poster Session

18-21 March 2018 ● Lisbon, Portugal

DATA MANAGEMENT GROUP—POSTER SESSION

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Strategies for more effective data acquisition

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Background: What are the major problems in the process of data collection in centers and what can be done about it? This has been the starting point of a discussion within the Austrian Stem Cell Transplantation Working Group with the aim to facilitate data collection in centers. **Methods:** Representatives of the Austrian Stem Cell Transplantation Working Group have engaged in a process of discovering obstacles in the process of data reporting. We have summarized the main arguments of this discussion and identified several problem areas that need to be dealt with. **Results:** An important issue are cases that have not been documented well in the patient files. Sometimes this happens if patients have been transferred from other institutions or countries. Other reasons for incomplete documentation are lack of personnel for documentation, very complex cases with unclear or uncertain diagnostic findings or very long disease histories. Additonal problems are caused by inappropriate IT infrastructure for medical documentation within a hospital, data managers who do not get trained or introduced to this field of medicine or frequent changes of the responsible person for data reporting, and not enough consulting by physicians who are hematopoietic stem cell transplant (HSCT) specialists. Reasons for these pitfalls are mainly inadequate funding and as a result a shortage of personnel. On the side of the consulting physicians, the major obstacle seems to be very limited time resources. **Conclusions:** As possible solutions for making the process of data collection more effective and less time consuming for all parties involved we recommend centers to: Support individuals in charge of data collection, start local training courses, introduce MED-A-reporting for data managers in German, create a template for the report of HSCT patients so that all MED-A-questions are included. If data acquisition is not possible in depth for all patients for all transplants within a center, agreement on the selected indications that will be covered in depth and others that will be covered more generally should be established in a center to allow reporting with continuous data quality.

Conflict of interest: The authors have nothing to disclose.

Problemas de recogida en el Reg Austriaco:

- Mala documentación en la Hª del paciente, por traslado a otros centros
- Complejidad de casos y problemas de interpretación de los resultados
- DM sin experiencia, cambios frecuentes de personal. Médicos sin suficiente dedicación a las dudas, problemas del registro
- Razones: **Escasez de recursos** y **tiempo** por parte de los médicos.

Recomendaciones:

- Cursos de formación
- Formularios en alemán, plantilla de informes en HC con datos requeridos.
- Priorizar y establecer grupos homogéneos para tener grupos registrados de forma homogénea.

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Austrian Stem Cell Transplantation Registry (ASCTR)—preparing for the future

B Lindner[1], C Peters[1], D Nachbaur[1], and H Greinix[1] on behalf of the Austrian Group for Stem Cell Transplantation
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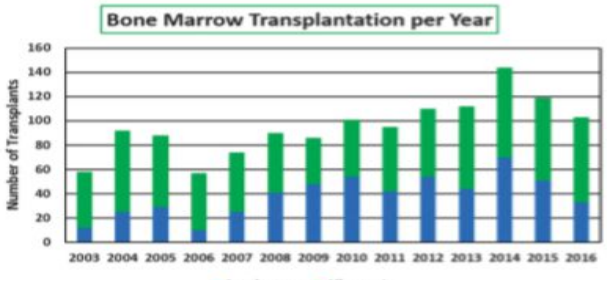
Since 2000, when Promise was introduced, the Austrian Stem Cell Transplantation Registry (ASCTR) has been using the EBMT database as national registry database. We have been collecting MED-A-Data of all HSCT performed in Austria since 1978 from all registered transplant centers, including by now 3832 allogeneic and 5897 autologous transplants. Main disease categories in the allogeneic setting are AML ($n=1233$) and Precursor Lymphoid Neoplasms ($n=665$), in the autologous setting NHL ($n=1384$) and Multiple Myeloma ($n=2190$). The ratio adult versus paediatric transplants is 8269 versus 1460. In addition, we use the EBMT data base for collecting data on family donor outcome. Furthermore, data on stem cell harvests has been collected locally since 2005. The ASCTR is obliged to report data on patient and disease demographics quarterly to the Austrian health authorities. For this purpose we keep these data in a local database that is linked to the EBMT database. Central data entry through the ASCTR includes immediate queries to reporting centers if data are missing or incorrect. Additional data quality checks are done on an annual basis when the data is analysed for the annual report on HSCT in Austria. This procedure has proved feasible and useful over the past years. So far, only two Austrian centers, both pediatric, have entered their data directly using Promise. All other Med-A data sets have been sent as paper version by the centers and have been entered centrally via the ASCTR. From 2017 onwards the Austrian centers are obliged to switch to online data entry, in accordance with the requirements of the EBMT to go paper free in 2017. We plan to do the necessary training courses for data entry within the first two to four months of the coming year, allowing a smooth transition. In order to encourage members of the Austrian Group for Stem Cell Transplantation (AGSCT) to use ASCTR data as starting point for new studies and other research projects, the ASCTR will focus on data quality issues including patient and disease demographics such as pretransplant comorbidities, disease stage, cytogenetic and molecular markers and follow-up reports to allow transplant outcome analyses that will be included in the annual report of the Ministry of Health in the near future. Each contributing center should have easy access to frequently needed analyses of their own data to be used for quality control of local transplant practices and for preparation of JACIE audits. Furthermore, donor follow-up data will be linked to a national database located at the transplant agency of the Ministry of Health to allow analyses on safety issues of hematopoietic stem cell donation and long-term side-effects. As an alternative to the use of EBMT database downloads for local analyses the establishment of a separate database combining all Austrian transplant and harvest centers has been discussed within the AGSCT. Besides being more costly, this strategy would result in decreased use of the EBMT database and centers, providing a minimum of data to EBMT since the vast majority of data collected would be stored in another database separate from EBMT. Hopefully, within due time a decision among our centers regarding database use will be made to foster further research projects and outcome analyses of both transplant recipients as well as donors.

Disclosure of conflict of interest: None.



- El Registro austriaco de TPH utiliza Promise como base de datos a nivel nacional. Envío de datos en papel hasta 2018 > registro centralizado > queries a centros (control de calidad)
- Desde 1978: **3832 Alo-TPH**, **5897 Auto.** Ratio adultos/pediátricos **8269** vs **1460**.
- Con esta información se atienden los requerimientos de JACIE y **organismos oficiales (actividad, resultados, biovigilancia donantes).**

- Desde 2018 registro directo en Promise (sin la validación intermedia del registro) > Retos para mantener el grado de registro y la calidad de la información

more accurate and timely service reporting, individual hospital benchmarking and transplantation research.
Disclosure of conflict of interest: None.

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The Challenges in Achieving Accurate MEDA Reporting for Multiple Myeloma Autologous Recipients

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Myeloma (MM) is the most common indication for autologous BMT in adults. Obtaining accurate diagnostic/follow up data to use in MEDA submissions can be challenging, since referral data can be patchy or inaccurate. (1) All 93 first autologous transplants performed by the South Wales Blood and Marrow Transplant Programme for MM in 2014 and 2015 were reviewed. Data on transplant protocols (reflecting referral data) was compared with source data obtained for EBMT MEDA reporting. 5 parameters were assessed: diagnosis date, myeloma subtype, disease status at BMT, Durie-Salmon stage, and HCT-CI score. (2) Data was extracted from electronic/paper records from referring hospitals. The results are summarised in Table 1. Inaccuracies were seen across all 5 parameters. For the exact date of diagnosis, only 46/93 (49.4%) had an accurate date; the rest were either inaccurate or were missing/incomplete. The inaccuracies ($n=25$, 26.9%) ranged from 1 day to 433 days; median $=15$ days. For disease status at BMT (using the International Myeloma Working Group response criteria), 17/93 (18.3%) were inaccurate. The inaccuracies were instances of responses being overstated ($n=10$) or understated ($n=7$). Post review: 7 were upstaged: PR-VGPR = 3, VGPR-sCR = 1 and CR-sCR = 3. 10 were down staged: CR-VGPR = 7 (6 due a lack of a negative immunofixation test/ bone marrow), VGPR-PR = 1, and PR-progression $n=2$. Inaccuracies in HCT-CI score ($n=7$, 9.6%) were simply down to clinicians not thoroughly checking pre-BMT tests against the HCT-CI criteria. In Durie-Salmon staging inaccuracies ($n=14$, 15.1%), 6 were a result of staging being applied when not technically possible i.e. not all diagnostic tests were actually performed. Six were stated as stage I/II, but post review were in fact stage III. Two involved differences between the A/B component (serum creatinine) of the staging. Most inaccuracies were attributed to clinicians not having access to the primary source data at time of transplant. Although requested at referral, compliance by referrers is generally poor. Source data is obtained by the Data Manager.

Table 1

Parameters Reviewed ($n=93$)
Exact Date of Diagnosis (Full date)
Accurate = 46 (49.4%)
Inaccurate = 25 (26.9%)
No date entered = 4 (4.3%)
Partial date (month and year) = 18 (19.4%)
Myeloma subtype
Accurate = 75 (80.6%)
Ig/Light chain type not documented = 18 (19.4%)
Disease status at BMT
Accurate = 74 (79.6%)
Inaccurate = 17 (18.3%)
Unclear = 2 (2.2%)
Durie-Salmon Stage
Accurate = 56 (60.2%)
Inaccurate = 14 (15.1%)
Missing = 23 (24.7%)
HCT-CI Score ($n=73$)
Accurate = 54 (74%)
Inaccurate = 7 (9.6%)
Missing = 12 (16.4%)

Data in referral letters is often at variance with source data. This probably reflects the practice of dictating letters without reference to the patients' records. Access to source data reveals inaccuracies in up to 26% of any given parameter. Although inaccuracies in reporting the date of diagnosis may not affect overall clinical outcomes. Inaccuracies in other parameters such as myeloma subtype, disease status at BMT, Durie-Salmon stage and HCT-CI are of particular importance and may have significance in the interpretation of registry data. The data shows the importance of having access to good data management support to allow accurate MEDA reporting.
Disclosure of conflict of interest: None

- MM principal indicación en Auto.
- 930 Autos entre 2014 y 2015 dentro del programa de TPH en el Sur de Gales.
- Se evaluaron 5 parámetros: Fecha Dx, Dx, est. D&S, status de enf, HCT-CI score.
- Fecha **exacta** del Dx **49,4%, parcial** (fecha y año) **19,4%, sin datos 4,3%.**
- **MM subtipo:** exacto **(80,6%),** sin info **(19,4%)**
- **Status enf:** exacto **(79,6%),** sin info **(20,5%)**
- **D&S:** Exacto **(6,2%),** sin info **(24,7%).**
- **HCT-CI score:** exacto (**74%),** sin info **(16,4%)**
- Mayoría inexactitudes debidas a que los clínicos no disponían del dato pre-TPH.
- Falta de exactitud en Dx no afecte a los resultados, pero si en parámetros como subtipo de Dx, estado enf al TPH, HCT-CI.
- Conclusión: Importancia de tener una **buena gestión de los datos** para disponer de **MED-A precisos**.

P741

Confounders of Consent: a Single-Centre Analysis of Predictors of Consent in a Stem Cell Transplant Service (SCT)

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Patient and outcome data collection is an integral component of participation in national and international SCT registries. Data reporting and research projects require prospective consent before collation and transmission. We performed an audit of consent for research data collection and transmission at our centre and identified factors associated with lack of consent status prior to SCT. Patients and Method: A retrospective cohort study identified 1,117 patients receiving 1,283 transplants between August 1987 and June 2016. Minimum follow-up was 100 days. 43.4% were consented and 56.6% were non-consented (i.e., deceased before consent [$n=403$], explicitly refused consent [$n=2$], alive and on active follow-up but did not respond [$n=114$], and lost to follow [$n=113$]). Factors contributing to consent status were identified and impact on survival outcomes was assessed. Results: Non-consented vs consented patients were significantly more likely to suffer post-transplant mortality (63.9% vs 27.2, $P<0.001$), be lost to follow-up (17.9% vs 14%, $P<0.001$), be from outside major city (29.3% vs 22%, $P<0.001$), be <61 y/o at first transplant (70.4% vs 60.4%, $P<0.001$), receive autologous cells as first transplant (74.7% vs 65.8%, $P<0.001$), to suffer more relapse (41% vs 34.6%, $P=0.003$) and die within 100days post-transplant (14.7% vs 1.9%, $P<0.001$). Median time to relapse is 293 days vs 364 days ($P=0.039$). Using logistic regression analysis, 71.1% ($P<0.001$) of variance in consent rates could be predicted by the significant variables with survival status and day 100 mortality being the most highly correlated variables predicting lack of consent. Overall survival (OS) rates ($P<0.001$) and disease-free survival (DFS) rates ($P<0.001$) were consistently higher for consented vs non-consented patients at all time points assessed post-SCT. (Figures 1, 2) Conclusion: High rates of non-consent in data collection and transmission may impact on the utility of national and international SCT databases. In this single-centre retrospective audit, high rates of non-consent were associated with younger age at transplant, regional residence and poorer outcome. This study highlights a selected cohort of patients who may benefit from additional strategies for obtaining consent for data collection and transmission prior to SCT.

Disclosure of conflict of interest: None.

- La recogida de datos y proyectos Inv. requieren C.Inf.
- Auditoria de C.Inf disponibles->factores asociados a la falta de los mismos.
- Estudio **retrospectivo**: n=1.117, (1283 TPH entre Ag´1987 y Jun´16)
- F-up (100d): **43,3%** C.inf Ok, **56,6%** sin C.inf (Dead antes de C.Inf n=403, no consiente n=2, perdida de F-Up n=113, vivos en d+100 pero sin respuesta n=114)
- Pacientes sin C. Inf más propenso a: Fallecimiento post-TPH **63,9%** vs **27,2%** (p<0.01), perdida de **seguimiento 17,9%** vs **14%** (p<0.01), ser de **fuera de la ciudad 29,3%** vs **22%** (p<0.01).
- Análisis regresión logística:71%(p<0.001)de diferencia entre los que consienten y no consienten en función de si vivos o no en d+100.
- OS vs DFS d+100 fueron más altas en los pacientes que habían consentido frente a los que no.
- **Conclusión:** altas tasas de no consentimiento asociadas a ser más jóven al TPH, residencia fuera de la ciudad y resultados de enfermedad peores.