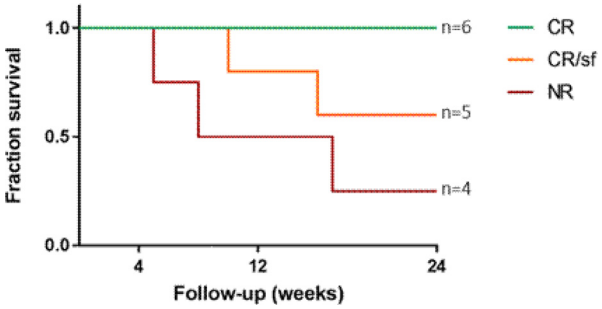

Figure 1. Kaplan-Meier curve for survival after FMT (n=15).

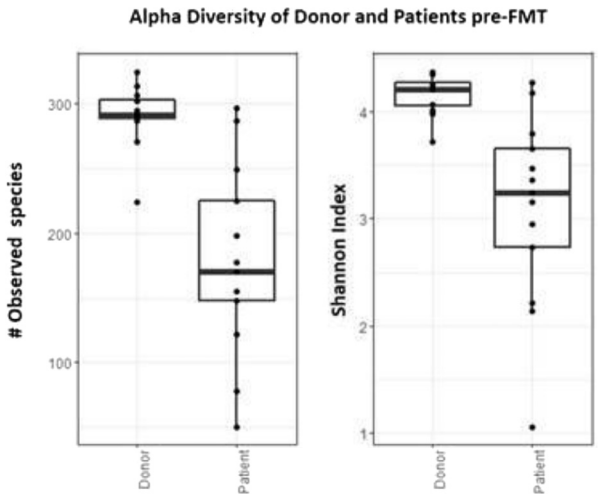

Figure 2. Alpha diversity depicted as number of observed species (left) or Shannon index (right) of donor and patient stool samples pre-FMT.

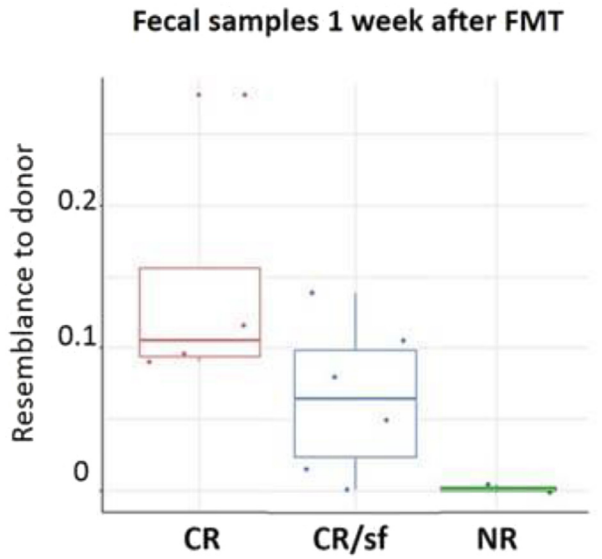

Figure 3. Resemblance of fecal microbial composition from complete responders (CR), CR with secondary failure (CR/sf) and non-responders (NR, n=4) to donor samples one week after FMT, represented by Jaccard similarity coefficient.

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Formation of a Dedicated Graft Versus Host Disease Committee to Improve Outcomes in Allogeneic Hematopoietic Cell Transplant Patients

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Graft Versus Host Disease (GVHD) is common, complex and at times difficult to differentiate from other complications. GVHD is the leading cause of non-relapse mortality after hematopoietic cell transplant (HCT). Current treatments for GVHD are only partially effective and response rates for first-line treatment of acute GVHD are < 50%. Clear and complete documentation of GVHD assessment is essential not only for reporting purposes, but also critical to early intervention to progress to next line of treatment sooner. The purpose of this project is to assess deficiencies in documentation across providers and implement a team-based approach to the care of our patients with GVHD.

A 12-person multidisciplinary GVHD committee was formed consisting of advanced practice providers, oncologists, and data and quality specialists. This committee meets monthly to systematically review all current cases of acute and chronic GVHD. Documentation review consists of date of incidence, maximum grade, treatment initiation, discontinuation and response to each line of treatment for weekly acute GVHD assessment and the completion of assessment at 100 days, 6 months, and 1 year for chronic GVHD. Documentation feedback and/or request for clarification is entered into the electronic medical record in the form of a documentation clarification entry. Additional efforts to promote a team based approach include GVHD educational opportunities to enhance assessment skills and discussion of treatment options, including GVHD clinical trials. Documentation review triggers an e-mail recommendation to the provider to consider referral to our chronic GVHD multidisciplinary clinic and the resources of a GVHD specialist.

Metrics used to evaluate this project include incidence and grade of acute GVHD, frequency of clarification requests, accuracy of provider documentation, and number of referrals to chronic GVHD clinic. Preliminary results at 6 months for 19 acute GVHD and 44 chronic GVHD cases reviewed indicate improved accuracy in documentation.

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Graft-Versus-Leukemia Effect after Haplo-Identical Stem Cell Transplantation with Post-Transplant Cyclophosphamide in Patients with AML- No Association with Graft-Versus-Host Disease (GVHD): A Study on Behalf of the Acute Leukemia Working Party of EBMT.

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Introduction: Allogeneic stem-cell transplantation (SCT) is curative therapy in AML by providing intensive chemotherapy and enhancing a graft-versus-leukemia (GVL) effect. The GVL effect is usually closely associated with GVHD. The use of haploidentical SCT (haploSCT) is rapidly increasing due to the introduction of non-T depleted methods, in particular with post-transplant cyclophosphamide (PTCy), with similar outcomes as following other donor sources. There is no data whether GVL after haploSCT is associated with GVHD as in matched donor SCT.

Methods: We assessed the impact of acute and chronic GVHD on SCT outcomes following non-T depleted haploSCT with PTCy, by using a series of landmark analyses.

Results: The study included 605 patients with AML in CR1 (73%) or CR2 (27%) after haploSCT with PTCy, given during the years 2009-2016. The median age was 53 years (18-76). The overall rate of acute GVHD grade II-IV and III-IV was 28.4% and 8.0%, respectively. The rates of chronic GVHD all grades and extensive were 32.7% and 12.3%, respectively. The 2-year leukemia-free survival (LFS) was 59.9%. 509 patients were alive and leukemia-free 100 days after SCT; 366 had no prior acute GVHD at this landmark, 107 had acute GVHD grade II and 36 had grade III-IV. The subsequent relapse rate was 20.3%, 18.3% and 11.9%, respectively (P=0.60). The subsequent non-relapse mortality (NRM) rate was 10.3%, 19.0% and 35.7%, respectively (P<0.001). LFS was 69.4%, 62.6% and 52.4%, respectively (P=0.01). Multivariate analysis showed that acute GVHD grade II was not associated with subsequent relapse (Hazard ratio (HR) 1.02, P=0.93), had borderline association with NRM (HR 1.79, P=0.09) and no association with LFS (HR 1.28, P=0.27). Acute GVHD grade III-IV was not associated with subsequent relapse (HR 0.92, P=0.87), but was associated with higher NRM (HR 5.23, P<0.001) and lower LFS (HR 2.35, P=0.003). 393 patients were alive and leukemia-free 6 months after SCT; 316 had no prior chronic GVHD, 55 had limited and 22 extensive chronic GVHD. The subsequent relapse rate was 14.3%, 9.2% and 23.9%, respectively (P=0.60). The subsequent NRM rate was 7.3%, 10.4% and 31.7%, respectively (P=0.003). LFS rate was 78.4%, 80.4% and 44.4%, respectively (P=0.01). Multivariate analysis showed that limited grade chronic GVHD was not associated with subsequent relapse (HR 0.69, P=0.44), NRM (HR 1.43, P=0.55) or LFS (HR 0.88, P=0.74). Extensive chronic GVHD was not associated with subsequent relapse (HR 1.44, P=0.56) but was associated with higher NRM (HR 5.77, P=0.004) and lower LFS (HR 2.75, P=0.01).

Conclusions: Acute and chronic GVHD of any grade were not associated with subsequent relapse. Acute GVHD grade III-IV and extensive chronic GVHD were associated with higher NRM and lower LFS. GVL is thus not closely associated with GVHD after non T-depleted haploSCT with PTCy. Future novel strategies for prevention of significant GVHD are warranted.

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Health Care Utilization and Financial Impact of Acute Graft-Versus-Host Disease (aGVHD) Among Children Undergoing Allogeneic Hematopoietic Cell Transplantation (alloHCT)

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Introduction: Steroids are the only effective treatment for acute GVHD and optimal salvage regimen for steroid refractory (SR) GVHD remains elusive. Impact of steroid sensitive (SS) and SR-AGVHD on healthcare utilization and cost is not well described.

Methods: In this is a single center study, we analyzed data on of 97/240 (40%) consecutive pediatric patients who developed grade I-IV AGVHD. Among patients with AGVHD, we analyzed cost, healthcare utilization and patient outcomes for the first year post-alloHCT. Costs were estimated from charges recorded in the PHIS database and hospital accounting.

SR-AGVHD was defined as failure to respond to steroid treatment. Failure to respond was defined as any Grade II-IV AGVHD that showed progression within 3 days or had no improvement within 7 consecutive days of treatment with 2 mg/kg/day methylprednisolone or equivalent.

Results: The median age of children with SS-AGVHD vs. SR-AGVHD was 9.44 years (0.26-21.0) vs. 12.2 years (0.42-21.0), p=0.204. The incidence of SR-AGVHD was 27%. Median time to onset of AGVHD was 28 days (6-232). AGVHD was grade III at diagnosis in 71% patients with SR-AGVHD vs. 29% patients with SS-AGVHD, P<0.001. Multiorgan involvement was more frequent among patients with SR-AGVHD compared to SS-AGVHD (42 vs.11%, p=0.03). Progression of acute into chronic GVHD was more frequent among patients with SR-AGVHD compare to SS-AGVHD (27 vs. 3%, p=0.001). The incidence of invasive fungal infection was statistically higher among patient with SR compared to SS-AGVHD (35 vs.15%, P=0.05). Salvage regimens utilized to manage SR-AGVH included 1, 2, and ≥3 drugs in 46%, 27%, 27% patients, respectively.

In multivariable analysis, patients with aGVHD had an average of 45.4 days (p<0.001) longer length of hospitalization compared to patients without aGVHD and added hospital costs of US$173,836 (p<0.001).

1-year OS for SR-AGVHD compared to SS-AGVHD was 50% (SE=9.81%) vs. 69.0% (SE=5.49%), p=0.046.

Conclusion: SR-AGVHD is associated with prolonged hospitalization, higher cost and inferior survival among children. Better AGVHD prevention strategies are desperately needed. Despite significant advances, lack of effective salvage regimens for SR-AGVHD remains a major concern.

	Steroid Responsive GVHD (n=71)	Steroid Refractory GVHD (n=26)	p-value
Hospital Length of stay (days)	95 (35-354)	144 (43-319)	0.004
PICU admission	43 (60.6%)	20 (76.9%)	0.156
Number of outpatient visits	42 (0-97)	33 (0-89)	0.253
Cost of Transplant admission	$170504 (85,704-781,744)	$186458 (13,126- 1,471,698)	0.201
Total inpatient cost	$338,215 (117,864-1,162,370)	$522818 (127,419- 1,471,698)	0.003