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Late Effects of Total Body Irradiation and Hematopoietic Stem Cell Transplant in Children Under Three Years of Age

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Abstract

Background—Total body irradiation (TBI) is an important component of hematopoietic stem cell transplant (SCT) for pediatric malignancies. With increasing survival rates, late effects of SCT become more important. Younger children may be at particular risk of late effects of radiation and SCT.

Methods—We retrospectively reviewed outcomes of children less than three years of age who received TBI as part of their preparative regimen for SCT at Children's Hospital Colorado. Clinical information including the date of last follow up, most recent lab values, and physiologic tests were extracted from the medical record.

Results—Of 81 patients who underwent SCT, 19 received TBI and of those, 15 were long-term survivors available for review. Late effects occurring in greater than 50% of the children included abnormalities involving endocrine, metabolic, renal, cataracts and neurocognitive systems. Other organs involved less commonly included liver, skeletal, and cardiac abnormalities. Solid tumors were a rare finding with only 1 patient developing a benign osteochondroma and no identified secondary malignancies.

Conclusions—TBI has been shown to be an important part of the preparative regimen for patients undergoing SCT. Our results, similar to other studies, suggest TBI in patients less than three years of age will likely result in multi-organ dysfunction including endocrine, metabolic, renal, eye, and neurocognitive abnormalities. A longitudinal study with standardized testing of these systems would further clarify the late effects concerns in this patient population.

Keywords

BMT; Late effects of cancer treatment; Radiation therapy; ALL; Total body irradiation

Introduction

Hematopoietic stem cell transplant (SCT) has become a standard treatment for some pediatric malignancies. For certain SCT indications, particularly acute lymphoblastic leukemia (ALL), total body irradiation (TBI) plays an important role as part of the

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The authors have no conflict of interest.

preparative regimen[1–3]. With increasing survival rates, the late effects of therapy become more relevant. Survivors of SCT in childhood are at risk for dysfunction in all organ systems, including cardiovascular, metabolic, pulmonary, endocrine, renal, gastrointestinal, dental, ocular, and neurocognitive, as well as secondary tumors (recently reviewed in [4]). The use of TBI may be associated with increasing the incidence and severity of many of these late effects. The age of the patient also may influence the risk of late toxicity, with children under three years of age potentially at higher risk. Despite this, there are relatively few studies specifically reporting the late effects of TBI on infants [5,6]. We report on the late effects of children under the age of three treated at our institutions who underwent SCT with a TBI based preparative regimen.

Methods

We retrospectively reviewed outcomes of children who received TBI in preparation for allogeneic SCT at the Children's Hospital Colorado and at the University of Colorado Denver from 1994 to 2010. We included patients less than three years of age at time of transplant who received TBI as part of the preparative regimen for SCT. Patients who underwent SCT for non-malignant disease were excluded. Long-term survivors were defined as having survived more than one year post transplant and have completed at least their 1 year post-transplant evaluation therefore patients who died within one year of transplant were excluded.

The Colorado Multiple Institutional Review Board approved this study. Clinical information including the date of last follow up, most recent lab values, and physiologic tests were extracted from the medical record. Long-term follow-up was variable, so not all children were tested in all areas. We report the number of children with an abnormality and the total number of children tested for the various organ systems discussed.

Results

Eighty-one children less than 3 years old underwent hematopoietic stem cell transplant; 56 of these had malignant disease. Nineteen of the 56 (33.9%) patients were treated with TBI as part of the preparative regimen. Four patients died within one year of SCT and were not evaluable for late effects. Thus, there were 15 patients who fit inclusion criteria for review; five males and ten females. The mean age at SCT was 1.4 years (range: 0.4 to 2.8). Mean time to last follow up after SCT was 7.4 years (range: 1.4–13.0) with a mean current age of 9.7 years. The most common diagnosis was ALL (66.7%) followed by AML (26.7%), with one patient diagnosed with non-Hodgkin's lymphoma (6.7%). One patient underwent 2 SCTs.

Eleven patients had CNS therapy prior to transplant: 7 patients received intrathecal chemotherapy alone, 1 patient received cranial irradiation alone, 3 received intrathecal chemotherapy and cranial irradiation. All patients received 1200 Gy for their TBI dose prior to SCT, there were no dose reductions for age. TBI was delivered in 2 Gy fractions twice a day over 3 days using 6MV photons with a dose rate less than 10 cGy/min. The children were treated under general anesthesia, AP/PA with custom lung blocks on both treatment fields to limit lung dose to 9 Gy. No kidney blocks were used. Four patients noted to have additional cranial boost radiation received an additional 1000 Gy for history of positive CNS disease for a total cranial exposure of 2200 Gy. Patient demographics are provided in Table I.

Treatment related late effects are summarized in Table II. The most frequent late effects, occurring in greater than 50% of the children, were endocrine, metabolic, renal, eye, and

neurocognitive abnormalities. The most common endocrine adverse outcome was growth hormone (GH) deficiency, identified in 11/12 (91.7%) patients evaluated with 71% of the tested patients falling under the 2.5th percentile on their respective growth curve. GH deficiency was identified by both GH stimulation studies as well as measurement of insulin-like growth factor-1 and results were interpreted in consult with endocrinology services. Hypothyroidism was also prevalent and found in 5/14 (35.7%) patients. Two patients had evaluation of their gonadal axis and were found to have elevated luteinizing hormone and follicle stimulating hormone. One of these patients met criteria for diagnosis of ovarian insufficiency with an FSH of 67 and LH of 35.6 and was treated with estrogen and progesterone replacement therapy. Additionally, while metabolic syndrome was not formally evaluated, elevated triglycerides were present in 69.2% of the patients (9/13).

Renal function was assessed using blood urea nitrogen (BUN), creatinine (Cr), and GFR or creatinine clearance (CrCl). 78.6% of patients had an elevated BUN with a mean of 27.7mg/dL. Two of those patients (14.3%) also had an elevated creatinine (1.1 and 1.4 mg/dL). Seven patients had report of estimated GFR or creatinine clearance. Of those, 1 patient had renal insufficiency with a CrCl of 75 ml/min (normal 95–123 ml/min for her age). One patient had renal failure requiring dialysis and eventually underwent kidney transplant. Of additional note, cataracts were found in 9 of the 13 patients (69.2%) assessed.

Neurocognitive testing was performed in 13 children at least one year after SCT. Deficits were found in a majority of patients, with 11/13 (85%) of the patients demonstrating some type of long-term neurocognitive complication (Table III). The most common deficit was language and/or speech delay, present in nine patients. Learning difficulties were reported in two patients and attention deficit disorder in three patients. Motor or coordination deficits were present in three patients. Intelligence Quotient (IQ) or Bayley Scales of Infant and Toddler Development scores were available for 10 patients (Table IV). The Bayley score is commonly used in assessment of patients 1–42 months of age in place of an IQ test and utilizes the same scale, with mean of 100 and standard deviation of 15. Four patients had baseline neurocognitive testing done prior to SCT, of these three had a decrease in IQ or Bayley score on their post-SCT evaluation. Six patients (60%) scored within normal limits (scores of 85–115) at last follow up. Three patients had scores of 70–84 points and therefore were considered mildly intellectually disabled. One patient with a score of 55 was considered severely intellectually disabled. Of the patients with an IQ score below normal limits, two of those patients had received additional cranial boost radiation for a total cranial exposure of 2200 Gy, including patient 1, noted to have the lowest IQ score of 55.

We found abnormalities in other organ systems, but they were less common than those described above. Liver dysfunction was identified in five of the 15 patients (33.3%). The most common abnormality identified was an elevated aspartate aminotransferase (AST) (4/5). Two patients had an isolated elevation in AST, one patient had elevated AST and alanine aminotransferase (ALT), and one patient had an elevated AST, ALT, and alkaline phosphatase (ALP). One patient had an isolated elevation in ALP. No abnormalities with bilirubin were found. Skeletal abnormalities, including osteoporosis, scoliosis and kyphosis, were found in four children. Cardiac abnormalities were present in two of 11 patients. One child had mild mitral and tricuspid regurgitation and one child had left septal hypertrophy, left and right ventricular hypertrophy, and left atrial enlargement based on ECG only. Only four children underwent formal pulmonary function testing and two of those showed a decreased FEV1/FVC consistent with mild obstructive disease. As all patients were treated with custom lung blocks to limit lung doses to 9 Gy, it is not felt this finding is related to the TBI. Secondary tumors were uncommon. Only one patient developed a benign osteochondroma and there were no secondary malignancies. Finally, Five patients experienced severe (grade 2–4) acute graft versus host disease (GVHD) while three patients

experienced mild acute GVHD (grade 0,1). Chronic GVHD was uncommon, with only two patients developing limited chronic GVHD.

Discussion

For children with high-risk leukemia who are undergoing allogeneic SCT, TBI as part of the preparative regimen has been shown in a large retrospective study [3] and two smaller randomized controlled trials [1,2], to improve outcomes when compared to myeloablative preparative regimens containing high dose chemotherapy alone. Survivors of SCT as young children suffer numerous late effects of therapy in a variety of organ systems. In our cohort of 15 children less than three years of age who received TBI as part of the preparative regimen for SCT, the most common late toxicities encompassed endocrine, metabolic, renal, eye and neurocognitive abnormalities. Similarly, the largest reported series of 17 young children, of which 11 received TBI, from the University of Minnesota found the most common complications were endocrine (GH deficiency 58.8%), dental (tooth mal-development in 47.1%), metabolic (dyslipidemias in 58.8%) and cataracts (47.1%) [6]. The Minnesota group found no significant difference in IQ, but there were statistically significant deficits seen in attention and fine motor skills. In another series of 42 children who received TBI, of which 9 were younger than 3 years old, common late effects were endocrine (testicular dysfunction in 78%; ovarian dysfunction in 37%), pulmonary (restrictive pulmonary disease is 74%) and cataracts (78%) [7].

Long-term endocrine abnormalities were especially common in our cohort of patients with 73% having at least one aberration. In particular, growth hormone deficiency was seen in 91%. With such a high rate of GH deficiency, it is not surprising that 71% of our cohort fit criteria for short stature, falling under the 2.5th percentile. This high rate of GH deficiency likely reflects the use of radiation, as TBI is known to be a risk factor for GH deficiency [8]. High dose chemotherapy cannot be completely excluded as contributing to the development of GH deficiency as there remains controversy regarding the role of high dose chemotherapy alone and growth failure. A published review of the endocrine abnormalities following SCT noted that the use of cyclophosphamide alone has not been associated with growth deficiencies, but the addition of agents such as busulfan has been shown in some studies to contribute to GH deficiency [9]. Additionally, growth failure was noted to coincide with other significant post-SCT complications such as chronic GVHD [9]. Our patient cohort received a various chemotherapy regimens tailored to their clinical presentation, however none of the patients evaluated received busulfan. Furthermore, few patients in our cohort experienced chronic GVHD. These findings further support the conclusion that TBI had a significant effect on the GH status of our patients. An additional potential contributing factor to short stature is direct skeletal damage causing growth retardation with recent literature review estimating that 20% of TBI patients develop growth retardation due to disrupted normal bone growth [10]. Based on our experience, we suggest that children less than three who receive TBI should be screened early in order to supplement growth hormone when necessary.

Dyslipidemia was a common long-term metabolic outcome. Nine patients (69.2%) in our cohort had elevated triglyceride levels. Previous studies have found higher rates of metabolic syndrome in children with leukemia who undergo SCT as compared to children who are treated with conventional chemotherapy alone [11,12]. Some data suggests that dyslipidemia may result directly from growth hormone deficiency [13–16]. In corroboration with this, data shows that early supplementation with growth hormone improves lipid profiles and subsequently decreases cardiovascular risk in GH deficient adolescents and adults [13–15]. Perkins et al found 58.8% of patients with growth hormone deficiency and 29.4% with elevated triglycerides, while 91% of our cohort had growth hormone deficiency

and 69.2% with elevated triglyceride levels [6]. Therefore, it may be important to screen infants who undergo TBI/SCT for GH deficiency not only to prevent short stature, but also to prevent increased cardiovascular risk. Furthermore, these findings highlight the importance of following current Children's Oncology Group Long-Term Follow Up Guidelines to monitor lipid profiles in patients at risk of metabolic syndrome, including patients who have received radiation, every 2 years (www.survivorshipguidelines.org).

TBI as a component of preparation for SCT is known to be more cataractogenic than chemotherapy alone [17–19]. Our cohort had a high rate (69.2%) of cataract formation that is similar to the rate (78%) seen in another series of 42 children who received TBI [7]. Additionally, steroids have been shown to influence the rate of cataract formation [17,18]. However, we did not stratify patients according to steroid use in this report. Aggressive screening for cataracts with appropriate intervention among infants who receive TBI is essential for preservation of vision. The use of eye shielding during TBI treatments is also a preventative option to be explored as recent data has shown eye-shields to decrease severity and increase latency time of cataract formation with no increase of CNS leukemia recurrence [20].

Radiation therapy in young children is known to have significant adverse effects on neurocognitive functioning [21]. Previously reported neuropsychological outcomes following SCT have been variable. Some data suggest that SCT involves relatively low risk of significant neurologic and cognitive deficits [6,22]. Perkins et al. found no significant difference in IQ measures in infants who underwent SCT, but did find deficits in attention, fine motor skills and visual-motor integration [6]. A larger study of 158 children who underwent SCT found no significant decrease in IQ over time for children under 3 who underwent transplant [22]. While TBI was correlated with a statistically significant decrease in verbal IQ, performance IQ, reading and spelling, the difference was on average, a clinically insignificant three-point decline in IQ over 5 years. In comparison, a report on 8 young children who received TBI prior to SCT found some combination of motor and cognitive deficits in all 8 children [23]. Academic issues ranged from mild reading delay to pronounced learning disability. This is in contrast to the same author's report on older pediatric patients, where there was no resulting neurocognitive deficit in the 12–17 age group and minimal decline in the 3–11 age group [24]. These data suggest that the immature brain may be more susceptible to global damage by TBI. Our cohort was difficult to assess given lack of both standardized testing and longitudinal data. Eleven of 13 patients had a documented neurocognitive deficit at follow-up. The most common finding was speech and/or language delay in nine patients. Motor deficits were present in two patients. Four out of 10 patients in this cohort had an IQ or Bayley score consistent with intellectual disability. Of these four, two had received a cranial boost, resulting in a higher dose of cranial radiation than would have been provided with TBI alone. Of the remaining two patients with intellectual disability, both had received prior therapy with intracranial chemotherapy, but it is not clear what how this contributes to their neurocognitive outcomes following SCT. These children often had deficits prior to transplant and the developmental difficulties may be unrelated to treatment. Regardless, it is clear this is a group at risk. Frequent assessment with appropriate intervention is especially important in infants who undergo TBI/SCT.

Our report is limited given the retrospective nature of the review. It is possible that as our followup interval increases, the incidence of the various late effects may increase. We were unable to compare our cohort to patients who did not receive TBI as the follow up testing at our institution varied significantly based on preparative regimen. However, our results suggest that a longitudinal study with standardized testing for medical and neurocognitive outcomes comparing patients with and without TBI would be beneficial.

In summary, the findings in this report suggest that total body irradiation in children less than three years of age contributes to endocrine, metabolic, renal, eye and neurocognitive abnormalities. Survivors should be closely monitored for these deficits and treated appropriately.

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Table I

Patient Demographics

Patient	Gender	Disease	Age at SCT	Donor	Age at last F/U	Years to F/U	Prior CNS Therapy
1	M	AML	2.0	UCB	11.3	9.3	IT/CB
2	M	AML	0.4	UCB	3.5	3.1	IT
3	F	ALL	2.3	MS	13.1	10.8	None
4	F	ALL	2.5	MS	9.8	7.3	IT/CB
5[a]	F	Large Cell Lymphoma	0.9	1.UCB 2.MUD	4.7	3.8	None
6	F	AML	1.9	UCB	10.5	8.6	IT
7	M	AML	1.5	MS	2.9	1.4	IT
8	F	ALL	1.6	UCB	13.9	12.3	IT
9	F	ALL	0.5	No record	13.5	13.0	IT
10	F	ALL	1.8	UCB	3.6	1.8	IT/CB
11	F	ALL	0.7	UCB	9.4	8.7	IT
12	F	ALL	1.5	UCB	11.6	10.1	None
13	M	ALL	0.7	UCB	10.1	9.4	CB
14	M	ALL	0.6	UCB	8.3	7.7	None
15	F	ALL	2.8	MS	6.1	3.3	IT

UCB, unrelated cord blood; MS, matched sibling; IT, intrathecal chemotherapy; CB, cranial boost radiation.

[a]indicates patient underwent two SCTs.

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Table II

Late effects following TBI/SCT in infants

Outcome	Number of patients/Number evaluated (%)
Hypothyroidism	5/14 (35.7%)
Growth Hormone Deficiency	11/12 (91.7%)
Short Stature	10/14 (71.4%)
Cataracts	9/13 (69.2%)
Dyslipidemia	9/13 (69.2%)
Hypertension	3/15 (20%)
Cardiac abnormalities	2/11 (18.2%)
Elevated BUN	11/14 (78.6%)
Elevated Creatinine	2/14 (14.3%)
Abnormal LFTs	5/15 (33.3%)
Skeletal Abnormalities	4/11 (36.4%)
Secondary benign tumor[b]	1/15 (6.7%)
Secondary malignant tumor	0/15 (0%)

[b] Secondary benign tumor: osteochondroma

Table III

Adverse neuropsychological outcomes following TBI/SCT in infants

Variable	Number of patients/Number evaluated (%)
Any neuropsychological abnormality	11/13 (84.6%)
Language/Speech delay	9
Learning	2
Attention	3
Motor/Coordination deficit	2
General developmental delay	4

Table IV

IQ or Bayley Score of Infant and Toddler Development

Patient	IQ	Bayley Scales of Infant and Toddler Development
1 [a]		55
2		70
3	93	
4 [a]	80	
5		88
8		83
12	113	
13 [a]	99	
14	109	
15	112	

Note: Scores reported are greater than one-year post SCT.

[a] indicates patient received additional cranial boost radiation.