

Author/ Year	Study Design	Demographics	Intervention, outcome measures; instruments	Results		Methodological Comments																
				Intervention group	Control group																	
Blum, 2001 (abstract)	Prospective, uncontrolled, unblinded cohort Inclusion/exclusion criteria not provided	N= 10 Demographic profile not stated	4-6 chemo cycles using various regimens, then TBI + G-CSF, then interferon alfa Outcome measures: survival; hematologic response; performance status; organ involvement	Median time from diagnosis to follow-up= 9 mos 100% survival within 100 days of transplant and at 6 mos Median survival from transplant= 18.5 mos 6 of 7 patients evaluable for hematologic response had complete response At last follow-up 5/10 alive with 3 in remission and 2 stable	None	Lack of a control group and randomization permits a number of sources of bias and confounding to be introduced into the study results, thereby decreasing the strength of the results and conclusions Small sample size Abstract-only format permits presentation of only limited study details																
Cassery, 2003	Prospective, non-randomized, concurrent control case series Control group= patients without end stage renal disease treated with AuSCT during the same period Inclusion: dialysis-dependent patients treated with hi dose melphalan and AuSCT Exclusion: EF<40, O2sat<95% on room air, performance status ≥ 3 , refractory CHF or arrhythmias	N=15 cases N= 180 controls Median age (n=15): 51 (range 40-67; 2 patients 64-67 y/o) %women (n=15): 47 Demographic profile not provided for control patients	Mobilization: G-CSF alone or with GM-CSF Conditioning: melphalan (dose adjusted for age, cardiac, and performance status) Outcome measures: complete hematologic response; survival	Overall hematologic response rate at 1 yr= 53% Hematologic response at 1 yr= 8/11 (evaluable) Overall median survival= 25 mos (p=0.1 v. control) <table border="1"> <thead> <tr> <th></th> <th>Survival (%)</th> </tr> </thead> <tbody> <tr> <td>1 yr</td> <td>~70</td> </tr> <tr> <td>2 yr</td> <td>~55</td> </tr> <tr> <td>5 yr</td> <td>~35</td> </tr> </tbody> </table> Peritransplant mortality (≤ 90 days from start of mobilization)= 13% Status of patients >63 yrs: <ul style="list-style-type: none"> the 67 y/o female had a complete hematologic response and died after 58 mos 		Survival (%)	1 yr	~70	2 yr	~55	5 yr	~35	<table border="1"> <thead> <tr> <th></th> <th>Survival (%)</th> </tr> </thead> <tbody> <tr> <td>1 yr</td> <td>~80</td> </tr> <tr> <td>2 yr</td> <td>~73</td> </tr> <tr> <td>5 yr</td> <td>~60</td> </tr> </tbody> </table>		Survival (%)	1 yr	~80	2 yr	~73	5 yr	~60	Lack of randomization, blinding. Small sample size
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				<p>post-transplant due to hemorrhagic CVA</p> <ul style="list-style-type: none"> the 64 y/o female had a complete hematologic response and is alive after 37 mos 																						
Dember, 2001	<p>Prospective, uncontrolled cohort study</p> <p>Inclusion: renal amyloidosis—urinary protein excretion >1 g/24h; age ≥18; EF>40</p> <p>Exclusion: dialysis-dependent</p>	<p>N= 65</p> <p>Median age: 57 (range 29-77)</p> <p>%women: 43</p>	<p>Mobilization: G-CSF</p> <p>Conditioning: melphalan (dose adjusted for age, cardiac, renal, pulmonary, and performance status)</p> <p>Outcome measures: urinary protein/24h; 24h Cr clearance; hematologic response</p>	<p>6/65 died during peritransplantation period (5/6 had symptomatic cardiac disease)</p> <p>50/65 (77%) alive at 1 yr; comparison of 1 yr survivors v. nonsurvivors: survivors younger (p=0.024), less # organs involved, received higher melphalan dose</p> <p>21/50 1-yr survivors had complete hematologic response</p> <p>%complete hematologic responders v. nonresponders who had a renal response at 1 yr: 71% v. 11% (p<0.001)</p>	None	<p>Lack of a control group and randomization permits a number of sources of bias and confounding to be introduced into the study results, thereby decreasing the strength of the results and conclusions</p>																				
Dispenzieri, 2001	<p>Primary analysis: retrospective case series to determine AuSCT eligibility and other clinical parameters as a prognostic factor</p> <p>Patients had to be AuSCT-eligible but not transplanted</p> <p>Secondary analysis of survival: 2:1 case-match-control (control= patients who were transplanted;</p>	<p>N= 229 cases N= 39 control</p> <p>Median age: 56 (range 25-70); 34% were older than 60 years</p> <p>%women: 42</p>	<p>Various chemo regimens</p> <p>Outcome measure: survival</p>	<p>Median time of follow-up= 52 mos (range 0.2-186 mos); Follow-up available for 96% of patients</p> <p>Median survival: 42 mos (95% CI, 43-57 mos)</p> <table border="1"> <thead> <tr> <th></th> <th>Survival rate-- % (95% CI)</th> </tr> </thead> <tbody> <tr> <td>6 mos</td> <td>83 (75-92)</td> </tr> <tr> <td>1-yr</td> <td>74 (65-85)</td> </tr> <tr> <td>2-yr</td> <td>61 (54-68)</td> </tr> <tr> <td>5-yr</td> <td>36 (30-43)</td> </tr> <tr> <td>10-yr</td> <td>15 (9-24)</td> </tr> </tbody> </table>		Survival rate-- % (95% CI)	6 mos	83 (75-92)	1-yr	74 (65-85)	2-yr	61 (54-68)	5-yr	36 (30-43)	10-yr	15 (9-24)	<table border="1"> <thead> <tr> <th></th> <th>Survival rate--% (95% CI)</th> </tr> </thead> <tbody> <tr> <td>6 mos</td> <td>85 (74-97)</td> </tr> <tr> <td>1-yr</td> <td>77 (65-91)</td> </tr> <tr> <td>2-yr</td> <td>68 (53-87)</td> </tr> </tbody> </table> <p>(No statistically significant differences)</p>		Survival rate--% (95% CI)	6 mos	85 (74-97)	1-yr	77 (65-91)	2-yr	68 (53-87)	<p>Lack of a control group and randomization permits a number of sources of bias and confounding to be introduced into the study results, thereby decreasing the strength of the results and conclusions</p>
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	<p>matched by age, sex, # involved organs)</p> <p>Inclusion: age ≤ 70, ventricular septal thickness ≤ 15 mm, EF > 55, serum Cr ≤ 2.0 mg/dL, symptomatic, organ involvement</p> <p>Exclusion: multiple myeloma</p>			<p>3 clinical parameters predictive of poor prognosis: increasing # involved organs, worsening performance status, ≥ 10 lb weight loss</p>																																						
Dispenzieri, 2003	<p>Retrospective analysis of prognostic value of serum cardiac troponin levels</p> <p>NOT a clinical study of autologous stem cell transplantation</p>	Not relevant	None	None	None	None																																				
Dispenzieri, 2004	<p>Retrospective case-match-control</p> <p>Patients who underwent transplantation were matched 1:1 to patients who did not receive transplantation</p> <p>Matching based on age, gender, time to presentation, EF, serum Cr, ventricular septal thickness, nerve involvement, 24-h urine protein, serum alk phos</p>	<table border="1"> <thead> <tr> <th></th> <th>Case</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>N</td> <td>63</td> <td>63</td> </tr> <tr> <td>Males, n (%)</td> <td>36 (57%)</td> <td>36 (57%)</td> </tr> <tr> <td>Median Age, y (range)</td> <td>53 (30-69)</td> <td>53 (32-69)</td> </tr> </tbody> </table> <p>Only variables with a statistically significant difference between groups were time from diagnosis to transplantation/treatment: 4.4 v 1.4 mos (case v control), and EF ≤ 50 (6 v 19% , case v control)</p>		Case	Control	N	63	63	Males, n (%)	36 (57%)	36 (57%)	Median Age, y (range)	53 (30-69)	53 (32-69)	<p>Mobilization: cyclophosphamide + GM-CSF or G-CSF alone</p> <p>Conditioning: melphalan + TBI or melphalan alone (various dose levels)</p> <p>Outcome measures: mortality within 100 days of transplantation; overall survival rate</p>	<p>Mortality within 100 days of transplant was 13%</p> <p>Median follow-up from diagnosis: 3.8 yrs</p> <table border="1"> <thead> <tr> <th></th> <th>Case (n=63)</th> </tr> </thead> <tbody> <tr> <td># deaths</td> <td>16</td> </tr> <tr> <td>Overall survival rate from transplant date (%)</td> <td></td> </tr> <tr> <td>1 yr</td> <td>82*</td> </tr> <tr> <td>2 yr</td> <td>81*</td> </tr> <tr> <td>4 yr</td> <td>70*</td> </tr> </tbody> </table> <p>*P<0.001</p> <p>4 case patients were ≥ 65 y/o (66-69 y)— 1 died at 6.3 mos while other 3 cases are alive after 35, 36, & 38</p>		Case (n=63)	# deaths	16	Overall survival rate from transplant date (%)		1 yr	82*	2 yr	81*	4 yr	70*	<p>Median follow-up from diagnosis: 8.8 yrs</p> <table border="1"> <thead> <tr> <th></th> <th>Control (n=63)</th> </tr> </thead> <tbody> <tr> <td># deaths</td> <td>44</td> </tr> <tr> <td>Overall survival rate from start of treatment (%)</td> <td></td> </tr> <tr> <td>1 yr</td> <td>68</td> </tr> <tr> <td>2 yr</td> <td>53</td> </tr> <tr> <td>4 yr</td> <td>40</td> </tr> </tbody> </table> <p>4 control patients were ≥ 65 y/o (66-69 y)— all 4 are dead (at 6.6, 6.8, 11.6, 42.6 mos)</p>		Control (n=63)	# deaths	44	Overall survival rate from start of treatment (%)		1 yr	68	2 yr	53	4 yr	40	<p>Not as robust as a randomized controlled trial. Impossible to control for all potential clinically important variables however this protocol appears to control well for the most important known variables.</p>
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Gertz, 2000	<p>Uncontrolled, unblinded prospective cohort</p> <p>Inclusion: total lifetime melphalan dose <500 mg; serum Cr <2.5 mg/dL</p> <p>Exclusion: multiple myeloma; moderate to severe CHF</p>	<p>N=23 mobilized; 20 transplanted</p> <p>Median age: 57 yr (range 37-70)</p> <p>%women: 30</p>	<p>Mobilization: cyclophosphamide + GM-CSF (1 patient received G-CSF alone instead)</p> <p>Conditioning: melphalan + TBI or melphalan alone</p> <p>Outcome measures: 50% decrease of 24-h urine protein excretion without increase in serum Cr; 50% decrease in serum alk phos without increase in transaminase level, bilirubin, or liver size; 2 mm decrease in ventricular septum thickness on echo</p>	<p>mos.</p> <p>3/23 tolerated mobilization poorly and were not transplanted: 1 died of progressive cardiac amyloidosis; 1 died of progressive hepatic amyloidosis; 1 developed severe GI toxicity and end-stage renal disease requiring hemodialysis</p> <p>After 3-30 mos (median 16 mos) follow-up 13/20 (65%) alive and 12/20 responders (median time to response= 4 mos)</p> <p>5/20 developed unexpected GI toxicity</p> <p>For patients >63 yrs: 1 (70 y/o man) died 2 mos after transplant from pneumonia; 1 (65 y/o man) died 2 mos post transplant from progressive autonomic failure and aspiration; 1 (65 y/o man) is alive 4 mos post transplant with a positive hematological response</p>	Not applicable	Lack of a control group and randomization permits a number of sources of bias and confounding to be introduced into the study results, thereby decreasing the strength of the results and conclusions
Gertz, 2002	<p>Prospective, uncontrolled, case series</p> <p>Inclusion: patients who received AuSCT between Mar 1996 and Jan 2001</p> <p>Exclusion: asymptomatic, multiple myeloma</p>	<p>N= 66</p> <p>Median age: 54 (range 31-70)</p> <p>%women: 44</p>	<p>Mobilization: cyclophosphamide + GM-CSF, or G-CSF alone</p> <p>Conditioning: melphalan + TBI, or melphalan alone</p> <p>Outcome measures: included complete hematologic response, and various organ-based responses</p>	<p>Overall treatment-related mortality= 14%</p> <p>33/66 (50%) hematologic responses; 32 (48%) organ responses</p> <p>Serum Cr and number of involved organs found to be independently associated with mortality</p>	None	Lack of randomization, blinding and control significantly reduces the robustness of the data.

Hayes-Lattin, 2002	Case series	N= 4 Age range= 52-65 yr All men	Mobilization: chemo + G-CSF/GM-CSF Conditioning: chemo +/- TBI	2 cases of toxic megacolon 1 case of multi-organ system failure 1 case of mucositis	None	Due to lack of randomization, blinding, and control, case reports do not provide robust evidence to support net health outcome decisions.
Kumar, 2001	Retrospective medical record review Analysis of GI bleeding after autologous stem cell transplantation	N= 45 medical records Age range: 31-61 yrs Sex: 7 women	Mobilization: cyclophosphamide + GM-CSF or G-CSF alone Conditioning: melphalan + TBI or melphalan alone	9/45 cases identified diffuse esophagitis and gastritis most common source 2 reports of upper GI bleeding 3 reports of lower GI bleeding 4 reports of both upper and lower GI bleeding median duration to onset of bleeding: 9.5 days (range: 1-48 days)	None	Case reports do not provide robust evidence to support net health outcome decisions.
Lachmann, 2002 (abstract)	Prospective, nonrandomized, unblinded, 3-arm, active control	N= 186 Median age (y): 55 (AuSCT) 98 (VAD/C-VAMP) 33 (IDM)	55 given AuSCT; 98 given VAD/ C-VAMP; 33 given IDM Outcome measures: overall mortality; median survival; complete response	Median survival (entire group)= 59 mos Overall mortality and median survival not significantly different between 3 groups %deaths: AuSCT = 44% Complete response in 62% of 154 patients who survived 6 mos	Early mortality (not defined) great in the AuSCT and IDM groups, and in patients older than 55 or who have cardiac amyloidosis %deaths: VAD/C-VAMP= 43% IDM= 39%	Lack of blinding and randomization limits the robustness of the data and any conclusions drawn from the data Abstract-only format permits presentation of only limited study details
Santhorawala, 2003	Prospective, stratified by predominant organ involvement and time from diagnosis to referral, randomized, 2-arm	N= 100 (52 Arm 1; 48 Arm 2) Median age: 57 Arm 1; 55 Arm 2 (range not provided)	Mobilization: G-CSF Conditioning: melphalan Outcome	Patient characteristics were similar between the 2 arms except for median time from enrollment to AuSCT 9 patients did not complete treatment: 4 withdrew, 2	16 patients did not complete treatment: 1 withdrew, 2 withdrawn for unrelated disease, 6 died, 3 with disease progression, 4 too ill to proceed.	Well-controlled trial. Median age is below 65 yrs with no indication of # of patients who were 65 yr or older limits

	<p>design comparing hi dose melphalan/AuSCT with or without prior oral chemo</p> <p>Arm 1: hi dose melphalan + AuSCT</p> <p>Arm 2: oral melphalan + prednisone, then hi dose melphalan + AuSCT</p> <p>Inclusion: newly diagnosed with primary amyloidosis; EF>40; no limit on renal status if other criteria were met; ≥1 organ involvement</p> <p>Exclusion: diagnosis of multiple myeloma</p>	<p>%Women: 35 Arm 1; 38 Arm 2</p>	<p>measures: survival; hematologic response; clinical response per organ</p>	<p>died, 3 too ill to proceed</p> <table border="1" data-bbox="1108 133 1409 852"> <thead> <tr> <th></th> <th>Arm 1</th> </tr> </thead> <tbody> <tr> <td>Treatment-related mortality</td> <td></td> </tr> <tr> <td>Pre-SC collect</td> <td>0 (0%)</td> </tr> <tr> <td>SC mobiliz/collect</td> <td>5 (10%)</td> </tr> <tr> <td>Death within 90 days of AuSCT</td> <td>5 (10%)</td> </tr> <tr> <td>Overall Survival</td> <td></td> </tr> <tr> <td>1 yr</td> <td>67%</td> </tr> <tr> <td>2 yr</td> <td>60%</td> </tr> <tr> <td>4 yr</td> <td>51%</td> </tr> <tr> <td>5 yr</td> <td>51%</td> </tr> <tr> <td>Median Survival @ 45 mos</td> <td>Yet to be reached</td> </tr> <tr> <td>Complete hematologic response @ 1 yr</td> <td>32%</td> </tr> </tbody> </table> <p>(No statistically significant differences)</p>		Arm 1	Treatment-related mortality		Pre-SC collect	0 (0%)	SC mobiliz/collect	5 (10%)	Death within 90 days of AuSCT	5 (10%)	Overall Survival		1 yr	67%	2 yr	60%	4 yr	51%	5 yr	51%	Median Survival @ 45 mos	Yet to be reached	Complete hematologic response @ 1 yr	32%	<table border="1" data-bbox="1438 105 1722 885"> <thead> <tr> <th></th> <th>Arm 2</th> </tr> </thead> <tbody> <tr> <td>Treatment-related mortality</td> <td></td> </tr> <tr> <td>Pre-SC collect</td> <td>6 (13%)</td> </tr> <tr> <td>SC mobiliz/collect</td> <td>7 (15%)</td> </tr> <tr> <td>Death within 90 days of AuSCT</td> <td>4 (8%)</td> </tr> <tr> <td>Overall Survival</td> <td></td> </tr> <tr> <td>1 yr</td> <td>56%</td> </tr> <tr> <td>2 yr</td> <td>54%</td> </tr> <tr> <td>4 yr</td> <td>50%</td> </tr> <tr> <td>5 yr</td> <td>39%</td> </tr> <tr> <td>Median Survival @ 45 mos</td> <td>37 mos</td> </tr> <tr> <td>Complete hematologic response @ 1 yr</td> <td>30%</td> </tr> </tbody> </table>		Arm 2	Treatment-related mortality		Pre-SC collect	6 (13%)	SC mobiliz/collect	7 (15%)	Death within 90 days of AuSCT	4 (8%)	Overall Survival		1 yr	56%	2 yr	54%	4 yr	50%	5 yr	39%	Median Survival @ 45 mos	37 mos	Complete hematologic response @ 1 yr	30%	<p>generalizability of results for this age range.</p> <p>Focus of this trial was on timing of AuSCT and not on comparing AuSCT v. non-AuSCT. Nevertheless, there was a trend toward a survival disadvantage for patients who received oral chemo first, especially in patients with cardiac disease.</p>
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<p>Seldin, 2004</p>	<p>Prospective, nonrandomized, unblinded, quality-of-life assessment compared to age-matched population norms</p> <p>Purpose: determine if hematologic/clinical response after AuSCT accompanied by increase in QoL</p>	<p>N= 251 transplanted patients who completed baseline SF-36</p> <p>N= 210 age-matched transplant-ineligible patients (comparator group)</p> <p>N=82 transplant-eligible patients not transplanted</p> <p>Mean age (n=251): 56±9.5 yr Mean age (n=210): not provided Mean age (n=82): not provided</p> <p>Men/women for subgroups: not provided</p>	<p>Mobilization: G-CSF</p> <p>Conditioning: melphalan-- dose dependent on age or clinical status</p> <p>Outcome measures: quality-of-life as measured by the physical and mental components of SF-36</p>	<p>104 AuSCT patients completed SF-36 at baseline and 1 yr; no apparent difference in clinical characteristics between this group and the group that did not complete SF-36</p> <p>84 completed at baseline and 2 yr; any difference in clinical characteristics between this group and the group that did not complete SF-36 not provided</p> <p>Physical component score: baseline: 34.5 1-yr: 41</p>	<p># transplant-ineligible who completed baseline and 1-yr or 2 yr SF-36 not provided</p> <p># transplant-eligible patients who completed a baseline, 1-yr, or 2-yr post transplant SF-36 not provided</p> <p>Physical and mental component scores at baseline, 1-yr, or 2-yr not provided for either the transplant-ineligible group or the transplant-eligible but not transplanted group</p>	<p>Lack of randomization and blinding.</p> <p>Incorrect comparator group—should be compared to transplant-eligible patients who did not receive an AuSCT</p>																																																

				<p>2-yr: 43 Mental component score: baseline: 45 1-yr: 52 2-yr: 51</p> <p>QoL significantly higher for patients who had complete hematologic response at 1-yr</p>		
Skinner, 2004	<p>Unblinded, non-randomized, 6-protocol-sequential, prospective cohort; transplant-eligible patients were compared to transplant-ineligible patients</p> <p>General inclusion: ages ≤ 80; compensated CHF; EF ≥ 40</p> <p>6 different protocols were used— protocols varied by age of patients included, melphalan dose given, degree of renal insufficiency allowed, type of cell collected, or timing of transplantation relative to chemo</p>	<p>Total n=701 (394 eligible; 307 ineligible)</p> <p>Mean \pm SD Age: 56.9 \pm 10.3 (eligible); 64.6 \pm 10.2 (ineligible)</p> <p>%Women: 41 (eligible); 40 (ineligible)</p>	<p>Mobilized with G-CSF</p> <p>Conditioning: melphalan-- dose dependent on age or clinical status</p> <p>Outcome measures: complete hematologic response at 1 yr; ≥ 2 mm decrease in cardiac IV septum or ≥ 1 class improvement in NYHA without increase in diuretic; $\geq 50\%$ decrease in 24-h urine protein excretion and $\geq 25\%$ decrease in serum Cr; ≥ 2 cm decrease in hepatomegaly on physical exam or disappearance of diarrhea and weight loss stabilized or reversed; improvement in sensory neuropathy on serial neuro exam;</p>	<p>Comparison of clinical features of eligible and ineligible cohorts revealed numerous statistically significant differences (e.g., age, # organ systems involved, performance status)</p> <p>Of 394 eligible for transplant, 312 were mobilized and 277 eventually transplanted</p> <p>Median survival of mobilized patients = 4.6 yrs; estimated 5-yr survival rate = 47% (95% CI, 39-54%)</p> <p>60/312 (19%) mobilized patients were ≥ 65 y/o— median survival was 4.9 yrs</p> <p>36/277 (13%) transplanted patients died within 100 days</p> <p>1-yr hematologic response (in 181 evaluable patients) = 40% (8% of these patients relapsed at 2 yrs)</p> <p>No difference in rate of responders seen in patients ≥ 65 yrs compared to younger patients</p>	Median survival = 4 mos	<p>Ineligible cohort is not an adequate control group because by protocol design these patients are not similar to the patients who were eventually transplanted.</p> <p>The results from 6 separate, different protocols were pooled. The differences in patient population and treatments given (e.g., melphalan dose) are likely to be significant confounders for the pooling of these results.</p>

			resolution of preexisting orthostatic hypotension; normalization of factor X level; ≥ 1 improvement in performance measure			
Versole, 2003 (abstract)	Uncontrolled, unblinded, multicenter registry	N= 114 Median age: 55 y (31-71)	Melphalan or TBI or other, then transplant Outcome measures: organ response at 100 days; 100 day mortality; overall survival at 1 yr and 3 yr	% organ response at 100 days: Hematologic= 33 Renal= 21 Hepatic= 32 Cardiac= 66 100 day mortality= 25% (95%CI, 17-33) across treatment regimens Overall survival at 1 y was 68% and at 2 yr was 57%	None	Lack of blinding and randomization limits the robustness of the data and any conclusions drawn from the data Abstract-only format permits presentation of only limited study details

Key

TBI-- total body irradiation
G-CSF—granulocyte colony stimulating factor
AuSCT—autologous stem cell transplantation
y/o—years old
mos-- months
GM-CSF—granulocyte, macrophage colony stimulating factor
EF—ejection fraction
Cr—creatinine
CHF—congestive heart failure
VAD— vincristine, Adriamycin, dexamethasone
C-VAMP—cyclophosphamide, vincristine, Adriamycin, methylprednisolone
IDM—intravenous low dose melphalan
QoL—quality of life
SF-36—short form-36
CI—confidence interval
Alk phos—serum alkaline phosphatase
SC—stem cell
NYHA—New York Heart Association