

<b>Study, country</b>
Di Lorenzo, 2009 Italy
<b>Study type, study period</b>
Randomised controlled trial.

June 2006 to May 2008.		
<b>Number of patients</b>		
80		
<b>Patient characteristics</b>		
Inclusion criteria: patients with high risk NMIBC failing BCG, where radical cystectomy was indicated but refused or inappropriate. Baseline characteristics:		
	<b>GEM (N = 40)</b>	<b>BCG (N = 40)</b>
<b>Male</b>	27	22
<b>Mean age, yrs</b>	69.3	71.4
<b>Stage Ta</b>	10	8
<b>Stage T1</b>	30	32
<b>Low Grade</b>	11	13
<b>High grade</b>	29	27
<b>Single tumour</b>	10	8
<b>Multiple tumours</b>	30	32
<b>Tumour &lt; 3 cm</b>	15	17
<b>Tumour &gt; 3 cm</b>	25	23
<b>Intervention</b>		
Intravesical gemcitabine (2,000 mg/50 ml) twice weekly for 6 weeks then once weekly for 3 weeks at 3, 6 and 12 months.		
<b>Comparison</b>		
Intravesical BCG (81 mg/50 ml) once weekly for 6 weeks then once weekly for 3 weeks at 3, 6 and 12 months.		
<b>Length of follow-up</b>		
Median follow up: 15 months		
<b>Outcome measures and effect size</b>		
Recurrence rate at 1 year follow up: 21/40 (55%) in GEM group vs 35/40 (87.5%) in BCG group, p = 0.002		
Time to first recurrence, months: 3.9 months (95% CI 3.0–7.0) in GEM group vs 3.1 months (95% CI 2.2–6.0) in BCG group		
Rate of radical cystectomy due to disease progression in patients with recurrent disease: 7/21 (33%) in GEM group vs 13/35 (37.5%) in BCG group, p = 0.12		
Incidence of grade 2 adverse events: 12/40 (30%) in GEM group vs 13/40 (32.5%) in BCG group, p = 0.12		
Incidence of grade 3 adverse events: 3/40 (7.5%) in GEM group vs 3/40 (7.5%) in BCG group, p = 0.25		
<b>Source of funding</b>		
Not reported.		
<b>Risks of bias</b>		
Selection bias: low risk		
Performance bias: low risk.		
Attrition bias: low risk		
Detection bias: low risk		
<b>Additional comments</b>		