

Impact of Gemtuzumab Ozogamicin on the Irish Healthcare System



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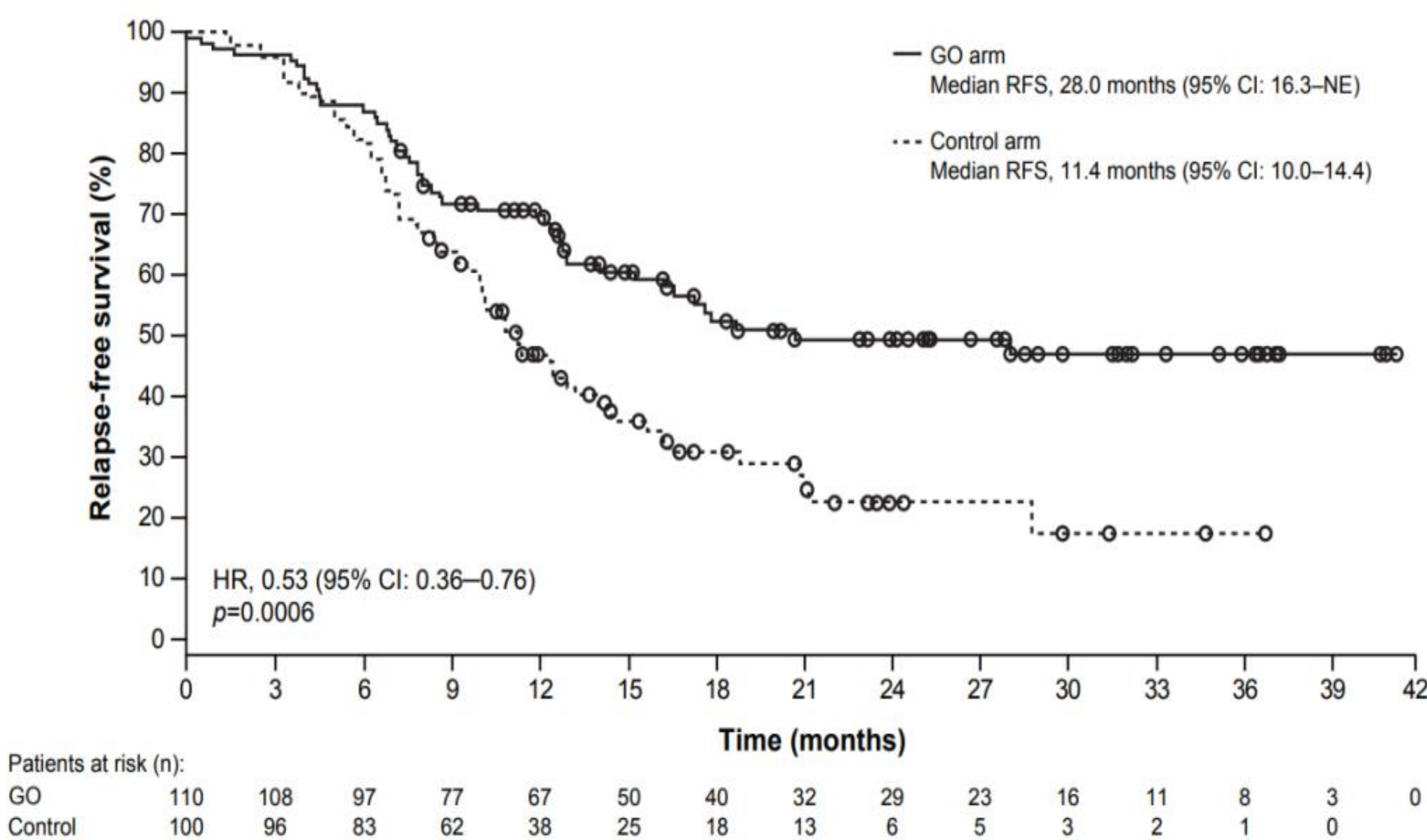
Introduction

Gemtuzumab ozogamicin (GO) was approved for use in combination with standard of care (SOC) (daunorubicin + cytarabine) for patients with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML) in April 2018 by the European Medicine Authority (EMA). GO is associated with a longer relapse free survival time and a more durable remission relative to SOC (1). The objective of this research was to estimate the clinical benefits and cost-offsets resulting from the potential introduction of GO in combination with SOC at a national level.

Methodology

Patient level data from the ALFA-0701 trial was used to develop a cost-utility and budget impact model examining the long-term effects of AML management. Economic cost inputs and analysis were from the perspective of the Irish healthcare system. Costs and resource utilisation were calculated as per HIQA guidelines (2). AML incidence rates were generated by applying international references to Irish population demographics. Estimates for treatment eligibility were sourced from practicing haematologists. Utility extrapolations were over a lifetime horizon (40 years). Budget impact estimates covered a 5 year period.

Figure 1 Relapse-free survival curve from ALFA-0701 trial (3)



Results

If all eligible patients in Ireland over a five-year period (estimate = 392) were to be treated with GO, it is projected to result in a quality-adjusted life-year (QALY) gain of 328 and 433 additional life-years gained (LYG) over their lifetime. It is estimated that approximately, 14 fewer haematopoietic stem cell transplants (HSCT) would be required during this five-year time horizon. This results in a reduction in expenditure of -€1,707,782 on HSCT. Additional disease management savings is estimated to be -€1,461,818 for patients requiring salvage therapy and -€1,783,200 requiring non-curative treatment.

Table 1 Impact of GO on Irish healthcare system

	GO + SOC	SOC
Total Eligible Patients		390
Overall QALY per patient	4.04	3.20
Overall LYG per patient	5.54	4.43
QALY increase(Population Level)		328
LYG increase (Population Level)		433
Number of HSCTs	43	57
Cost of salvage therapy	€7.03m	€8.49m
Cost of non-curative therapy	€6.79m	€8.57m
Cost of HSCT	€5.05m	€6.76m
*Total Relapsed / refractory expenditure	€18.87m	€23.82m

*includes Healthcare Expenditure associated with Salvage therapy, Non-Curative therapy and Transplant costs

Conclusions

The reimbursement of new and innovative medicines can result in increased medicine expenditure. However, investment in more effective therapies earlier in the treatment process can prevent downstream management costs for relapsed or refractory conditions.

In the case of GO, usage in the treatment of de-novo CD33 – positive adult AML in Ireland has the potential to both improve long-term patient outcomes and achieve downstream cost-offsets of €4.95m over a five-year period.

References:

1. Mylotarg Assessment Report. https://www.ema.europa.eu/en/documents/variation-report/mylotarg-h-c-4204-p46-003-epar-assessment-report_en.pdf
2. Guidelines for the Economic Evaluation of Health Technologies in Ireland 2019. HIQA Ireland. <https://www.hiqa.ie/reports-and-publications/health-technology-assessment/guidelines-economic-evaluation-health>
3. Lambert et al. Gemtuzumab ozogamicin for de novo acute myeloid leukemia: final efficacy and safety updates from the open-label, phase III ALFA-0701 trial. *Haematologica*. 2019 Jan;104(1):113-119.