



The MCL Biobank Observational Study comes of age

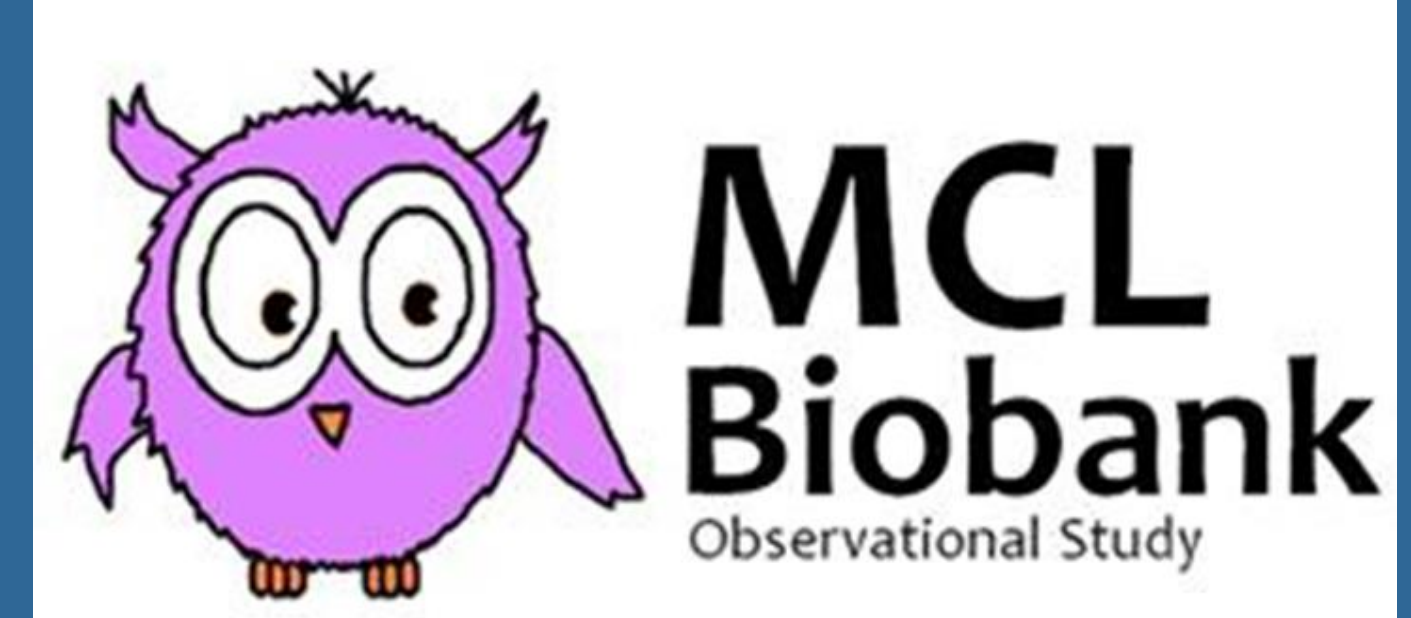
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INTRODUCTION

Mantle cell lymphoma (MCL) accounts for 6-8% of non-Hodgkin lymphoma and exhibits a heterogeneous clinical course. A subset of patients follow an indolent course allowing initial therapy to be deferred with no detrimental effect on survival¹. This group of patients classically present with extra nodal disease and are SOX11 negative².

This indolent subset is not accurately identifiable using existing prognostic scoring systems.

AIM

The MCL Biobank Observational Study is a prospective study designed to investigate differences between indolent and aggressive forms of MCL.

Newly diagnosed patients with MCL aged 16 and over were recruited from 73 NHS sites across the UK from October 2014 to October 2019. Patients were enrolled within 90 days of diagnosis and prior to receiving therapy.

Here we present an update of patient characteristics and outcomes from the MCL Biobank.

METHOD

Baseline patient characteristics, blood and saliva samples were collected at registration along with tissue blocks where available.

The primary outcome measure was time to treatment. Secondary outcome measures included overall survival (OS). Patients were followed up at a minimum of 6-monthly intervals. OS was defined as time from MCL diagnosis to death as a result of any cause or date to last follow up and was estimated using the Kaplan-Meier method.

We defined the watch and wait (W&W) subset as those patients that did not require treatment within 180 days of diagnosis.

Clinical data is held at the Peninsula Clinical Trials Unit and biological samples are stored at the University of Liverpool GCP Facility.

RESULTS

- A total of 593 patients were recruited. Patient characteristics are shown in Table 1.
 - Nineteen patients have been lost to follow up.
- Initial treatment was deferred for over 180 days in 218 patients.
 - The median time to treatment in this subgroup was 546 days (range 196-1847 days).
- The estimated median follow-up at the time of analysis was 1348 days.
- Sample availability is shown in Table 2.

Table 1: Patient Characteristics

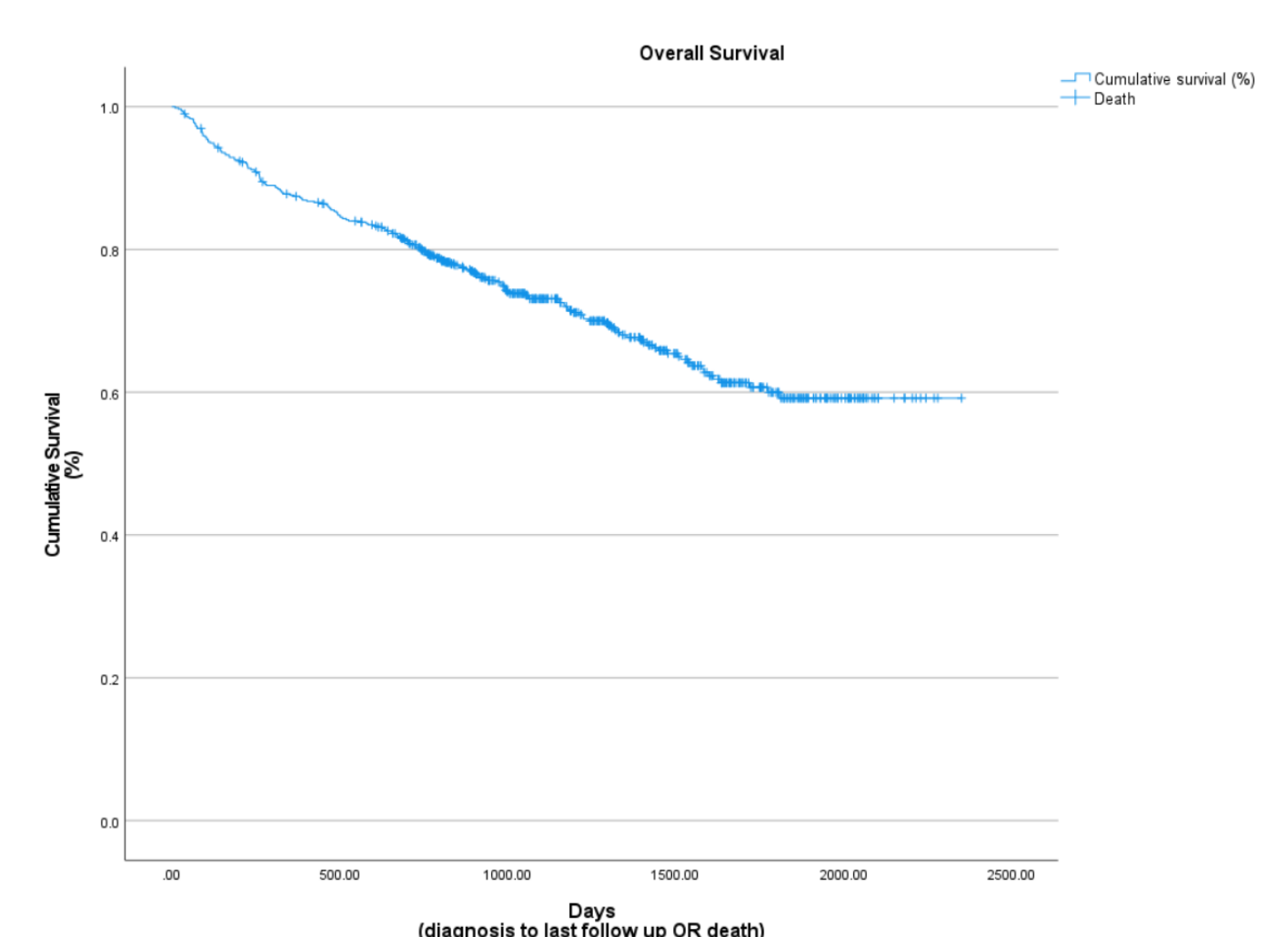
		All patients (n=593)	Early treatment (n=375)	W&W (n=218)
Characteristic		No.	No.	No.
Age (years)	Median	70	70	70
	Range	30-93	32-92	30-93
Sex	Male	426 (72%)	282 (75%)	144 (66%)
	Female	167 (28%)	93 (25%)	74 (34%)
Ann-Arbor Stage	I-II	87/569 (15%)	30/365 (8%)	57/204 (28%)
	III-IV	482/569 (85%)	335/365 (92%)	147/204 (72%)
ECOG performance score	0	327/588 (56%)	180/371 (49%)	147/217 (68%)
	1	197/588 (34%)	146/371 (39%)	51/217 (23%)
	2	49/588 (8%)	38/371 (10%)	11/217 (5%)
	3	15/588 (3%)	7/371 (2%)	8/217 (4%)
Bone marrow involvement		271/347 (78%)	202/252 (80%)	69/95 (73%)
Elevated LDH		201/561 (36%)	166/360 (46%)	35/201 (17%)
Lymphocytosis (>4.0 x 10 ⁹ /L)		190/590 (32%)	128/375 (34%)	62/215 (29%)

Table 2: Sample Availability

Sample		Treatment status of patient	
Type	No. collected	Treated	W&W
Tissue block	419	83%	17%
Blood	539	82%	18%
Saliva	572	83%	17%

- Initial analysis shows Rituxumab/Bendamustine (n=89) and R-CHOP (n=76) were the most commonly used regimens.
- 107 patients received treatment within the ENRICH study.

Figure 1: Estimated Overall Survival by Kaplan Meier survival Analysis



OS was 59.1% (median not reached)
3-year OS was 73.1% (95% CI 69.63-76.57%)

CONCLUSIONS

The MCL Biobank Observational Study creates a unique national database and tissue repository for further characterising indolent and aggressive forms of MCL.

With further analysis and collaboration, we seek to elucidate further biological differences between indolent and aggressive disease and, in doing so, discover and validate novel predictive markers and drug targets that will pave the way to a more tailored approach to therapy and disease monitoring.

REFERENCES

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