

Background

- Leptomeningeal Disease is a devastating complication of Breast Cancer.
- Median survival after diagnosis is two to three months¹.
- Standard Of Care (SOC) methods to diagnose LMD are cytology, MRI and Clinical Evaluation, which suffer from limited sensitivity and specificity and are unable to adequately monitor the response to treatment of the LMD tumor.
- The CNSide assay is a platform that captures tumor cells in the CSF, yields a quantitative CSF tumor cell result and can detect actionable mutations of CSF tumor cells.
- Here we present how CNSide was used to manage LMD in patients with breast cancer who were treated at four different intuitions and demonstrate its impact on clinical management.

Methods

- CSF of four (4) unique patients with breast cancer having suspected LMD was collected in Biocept's CEE-Sure™ tubes
- CSF was analyzed by CNSide for tumor cell number and presence of HER2 amplification by FISH on the CSF tumor cells²
- Patients were treated at the Smilow Cancer Hospital at New Haven (n=1 patient), Northwestern Medicine Lou and Jean Malnati Brain Tumor Institute and UT Southwestern (n=1 patient), and Barrow Neurological Institute (n=2 patients).
- All patients received Intrathecal (IT) treatment via an Ommaya reservoir

Patient Characteristics

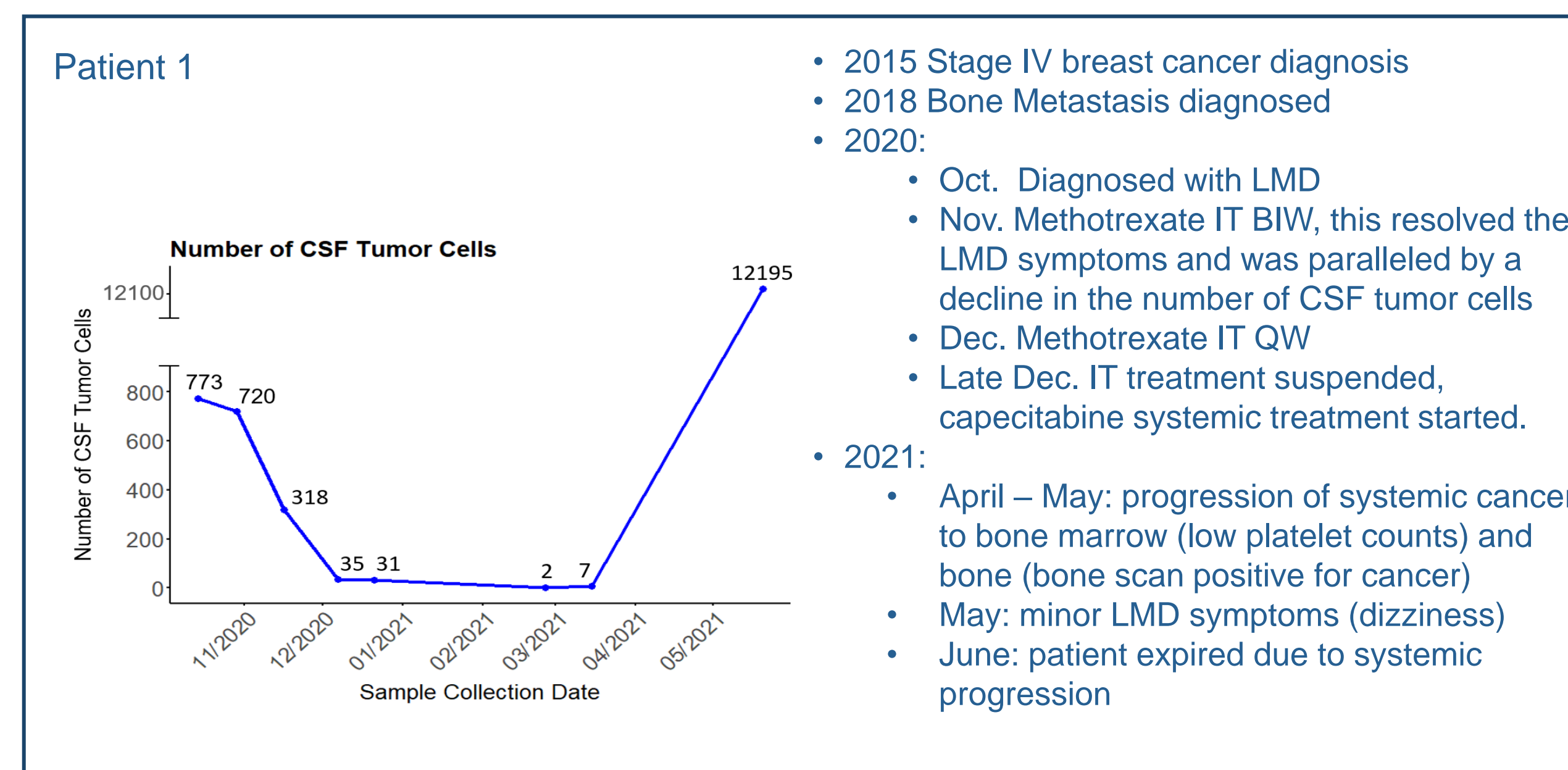
Patient Number	Gender	Age	Primary Tumor	Institute
1	F	48	BRCA2 Positive, ER/PR Positive, HER2 Negative	Smilow Cancer Hospital at New Haven
2	F	57	BRCA2 Positive, ER/PR Negative, HER2 Negative	Barrow Neurological Institute
3	F	45	ER/PR Positive, HER2 Positive,	
4	F	32	ER Positive, HER2 Negative	Northwestern Medicine Lou and Jean Malnati Brain Tumor Institute and UT Southwestern

Comparison CSF Tumor Cell Detection by CNSide vs Cytology

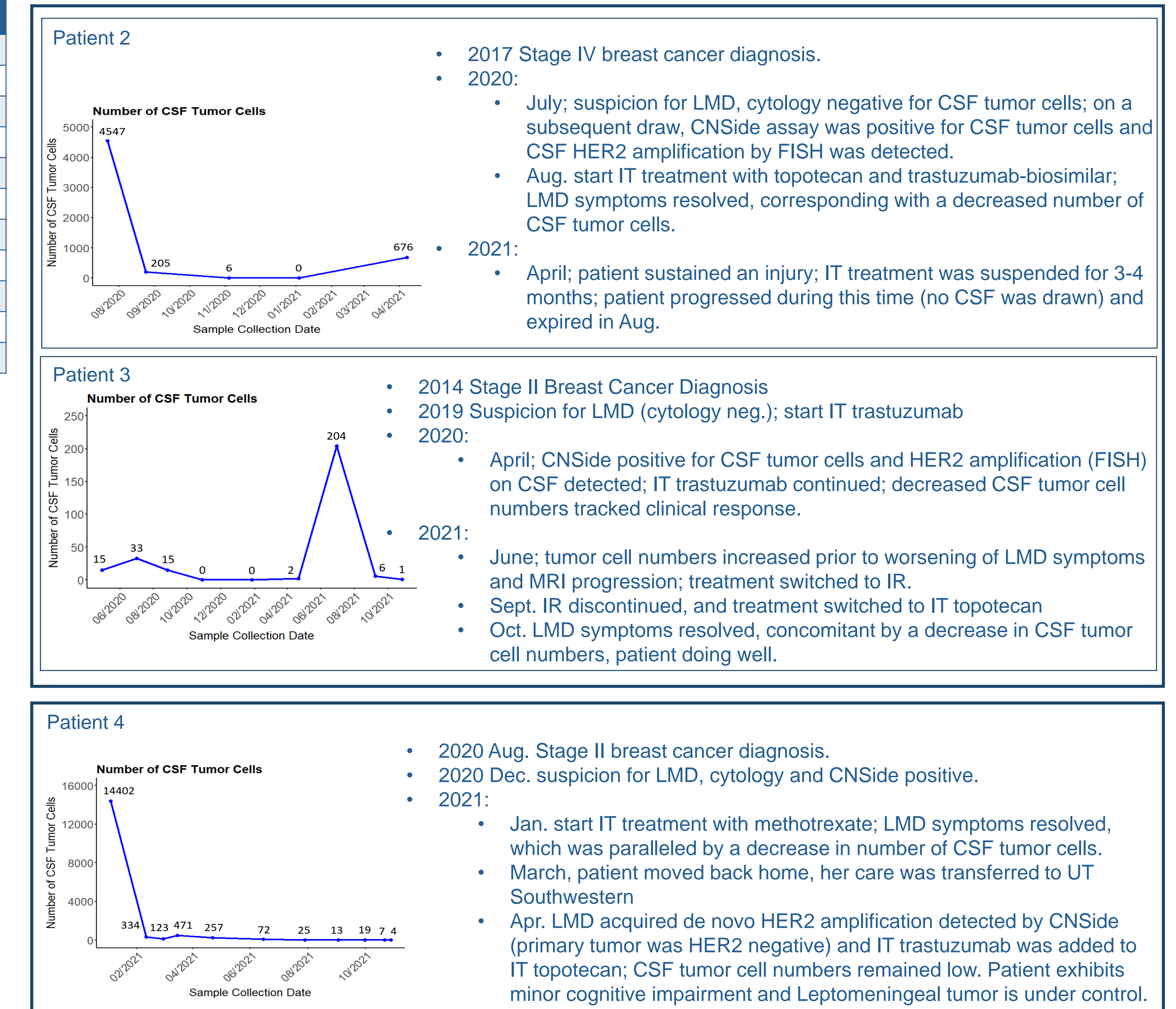
Patient Nr.	CSF Draw Nr.	Cytology (Positive, Negative, Atypical)	CNSide (Positive, Negative)
1	1	Positive	Positive
	2	Atypical	Positive
	3	Negative	Positive
	4	Negative	Positive
	5	Negative	Positive
	6	Negative	Positive
	7	Negative	Positive
	8	Positive	Positive
4	1	Positive	Positive
	2	Positive	Positive
	3	Positive	Positive

- In eleven (11) matched CSF draws analyzed by CNSide and cytology in parallel, CNSide detected tumor cells in 100% (11/11) of the samples, whereas cytology detected tumor cells in 54% (6/11- including one sample with atypical cells) of the samples.
- For patient 1 at the second CSF draw, CNSide was positive for the detection of tumor cells, whereas cytology detected atypical cells.
- For patients 2 and 3 cytology and CNSide was not performed on matched CSF draws.

CSF Tumor Cell Number Detection by CNSide during Treatment Tracks Clinical Response (Patient 1)



CSF Tumor Cell Number Detection by CNSide during Treatment Tracks Clinical Response (Patients 2, 3 and 4)



Conclusions

- Using CNSide for quantitative CSF tumor cell detection may aid in monitoring the response to treatment of the LMD tumor
- CNSide can detect actionable mutations of the CSF tumor cells, allowing targetable therapy to treat LMD
- CNSide may predict clinical progression prior to MRI evidence of progression
- Larger prospective controlled clinical trials are needed to further establish the role of CNSide in managing LMD

¹ Cancer Medicine. 2020; 9:7935-7942

² BIOM- 08 Poster Annual Society of Neuro-oncology meeting 2020