

CLINICAL EXPERIENCE OF INTEGRATIVE IMMUNOTHERAPY CENTRED ON OLEIC ACID COMPLEXED WITH DE-GLYCOSYLATED VITAMIN D BINDING PROTEIN

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INTRODUCTION

► Proteins of milk such as α -lactalbumin and lactoferrin bind oleic acid (OA) to form complexes with **selective anti-tumour activity** (*Biochim Biophys Acta* 2013 pii: S1388-1981(13)00281-3).

► Another protein highly represented in milk, colostrum and blood, the vitamin D binding protein (DBP or Gc protein) is the precursor of a potent macrophage activating factor (DBP-MAF or **GcMAF**) and, in analogy with other OA-protein complexes, we postulated that OA-GcMAF complexes might have an activity greater than that of Gc-MAF alone.

► Here we describe a **clinical experience** treating patients with **advanced cancers** with an integrative **immunotherapy** centred on OA-GcMAF.

PATIENTS and METHODS

► At Immuno Biotech Treatment Centre, patients with advanced cancer are treated with **OA-GcMAF-based integrative immunotherapy**.

► OA-GcMAF (Goleic) is used in combination with a low carbohydrate, high protein diet (*Le Gamberi Foods*) that is known to slow tumour growth and prevent cancer initiation (*Cancer Res.* 2011 Jul 1;71(13):4484-93. doi: 10.1158/0008-5472.CAN-10-3973. *Epub* 2011 Jun 14.), fermented milk products containing naturally produced GcMAF (*Bravo Probiotic*), high vitamin D3 supplementation (*Front Oncol.* 2013 Sep 23;3:250), and low-dose acetylsalicylic acid (*Nat Rev Clin Oncol.* (2012 Apr 3;9(5):259-67).

► All of these approaches aim to **strengthen and activate the immune system** and can be considered complementary and not alternative to other anti-neoplastic therapeutic procedures that the patients may want to take into consideration.

RESULTS

► When the primary tumour or the metastasis could be accurately measured, it was observed, on average, a **decrease of tumour volume of about 25% in a week**.

► This rate of reduction is **fully consistent** with the results reported by Nonaka *et al.* (*J Surg Res.* 2012 Jan;172(1):116-22. doi: 10.1016/j.jss.2010.07.057. *Epub* 2010 Sep 17), who observed a **93% volume reduction** of human hepatocellular carcinoma after 3 weeks of subcutaneous injection with GcMAF. It is also consistent with the results reported for neoadjuvant chemotherapy (*AJR* 2005;184:1774-1781).

► Among the cases observed at Immuno Biotech, we present the cases of patients, each representative of common cancers for whom our integrative immunotherapy was remarkably effective. To our knowledge, **this is the first example** of actual images of tumour volume reduction following GcMAF immunotherapy.

BEFORE
treatment



AFTER
treatment



► A 58-year-old woman was diagnosed with **pancreatic adenocarcinoma**. Ultrasonography of the pancreas was performed to assess modifications of a lesion that we interpreted being the one described by a previous MRI, following our the integrative immunotherapy approach. Bearing in mind that measurements taken on ultrasonographic images may be affected by a number of variables, preliminary evidence appears to indicate a change from 0.924 ml to 0.517 ml. (*i.e.* -45%).



In addition, it was noticed an hypoechoic rim surrounding the lesion that can be interpreted as perilesional oedema as well as fibrotic reaction.

► One of the **inguinal lymphnodes** (on the left side), taken as representative, showed a decrease from 1.54 to 1.30 cm² (given the irregular shape of the lesion, we preferred to calculate the area instead of the volume; the approximate reduction was 16%).

BEFORE
treatment



AFTER
treatment

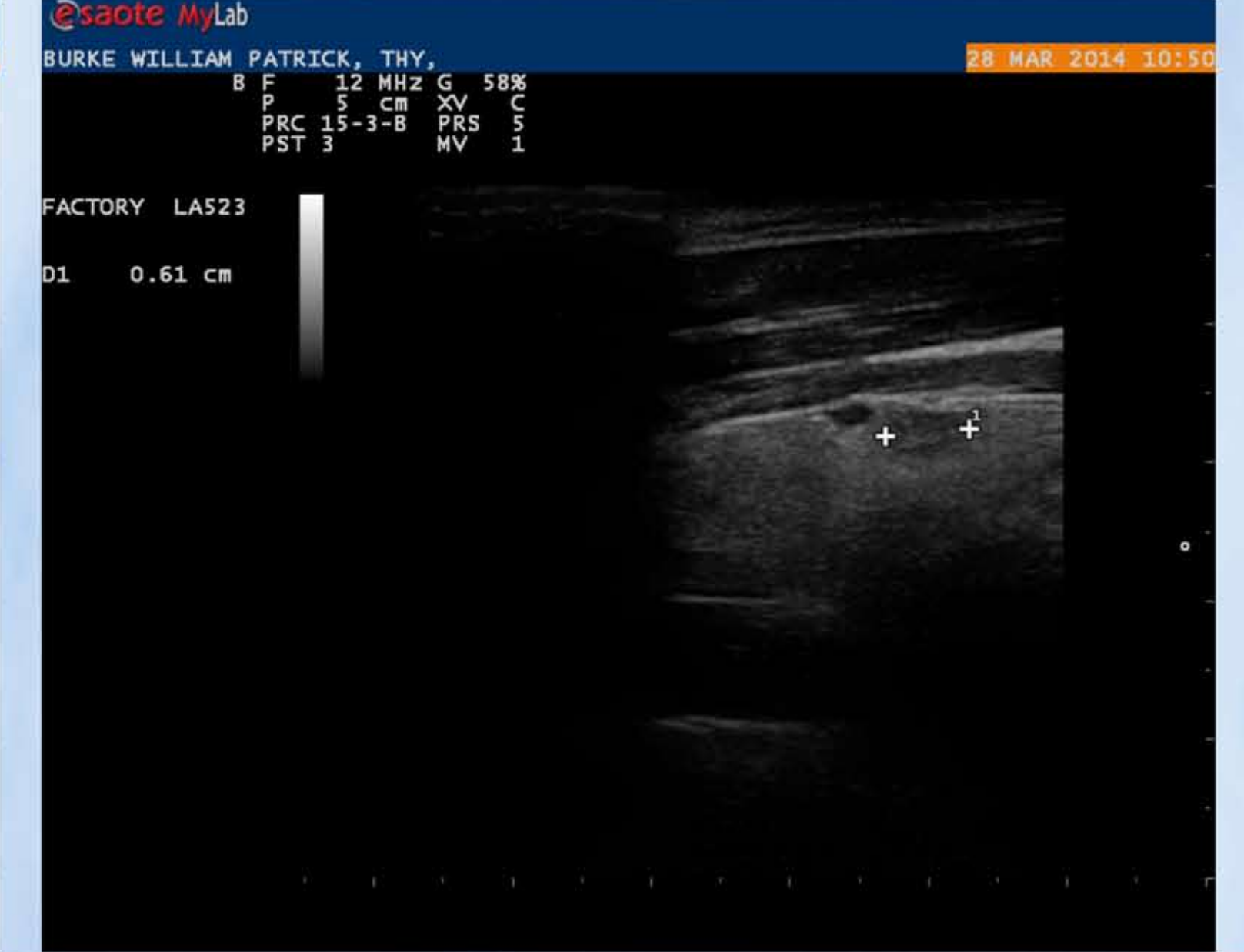


► A 80-year-old man was diagnosed with a **thyroid nodule**. Ultrasonography of the thyroid was performed to assess modifications of the solid nodule following the integrative immunotherapy approach. We noticed a significant reduction that corresponds to a calculated volume change around 27%.

BEFORE treatment



AFTER treatment



BEFORE treatment



AFTER treatment

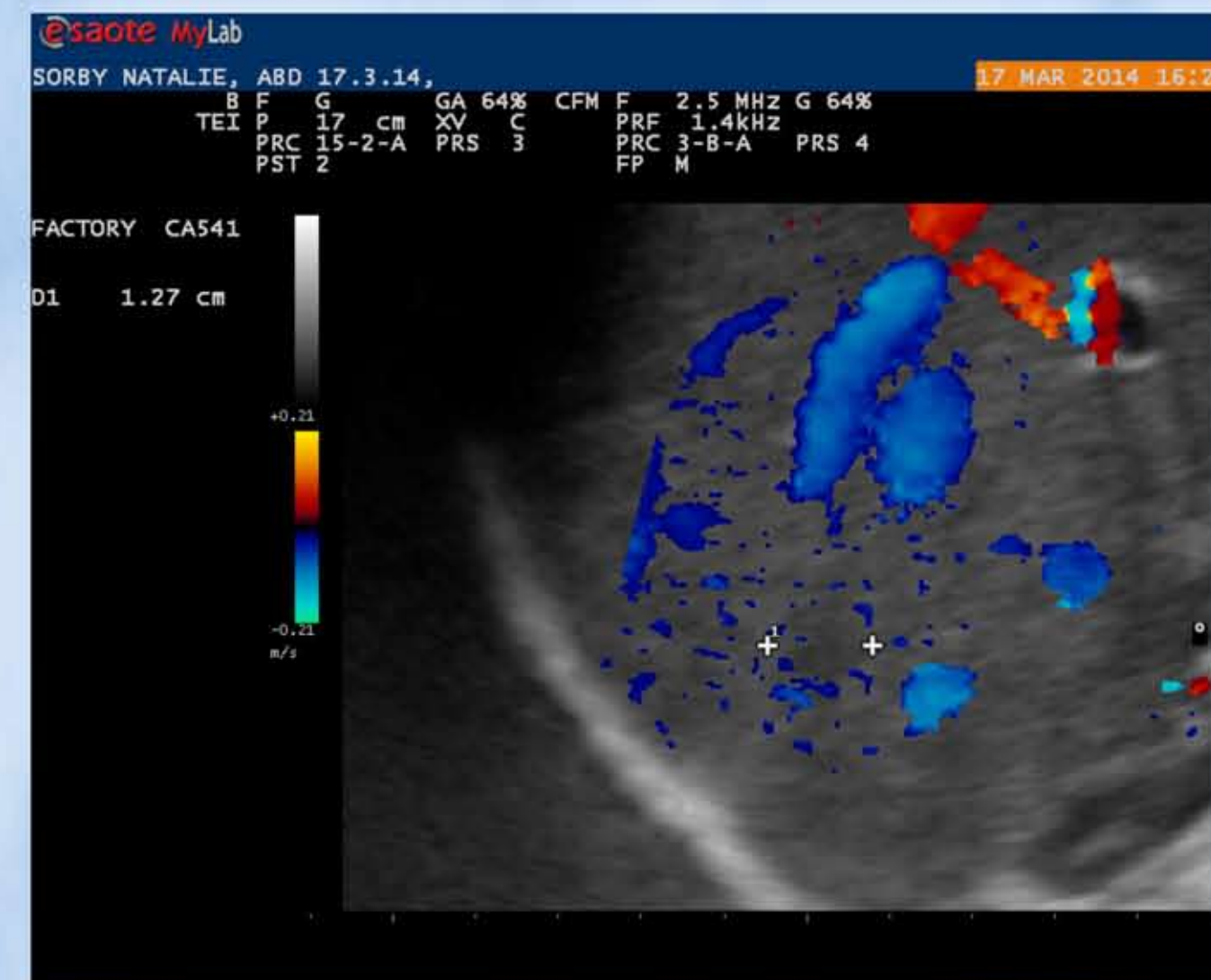


► 45-year-old male. **Metastatised rectal cancer**. Ultrasonography of the liver was performed to assess modifications of one of the metastases described in the radiology report, following the integrative immunotherapy approach.

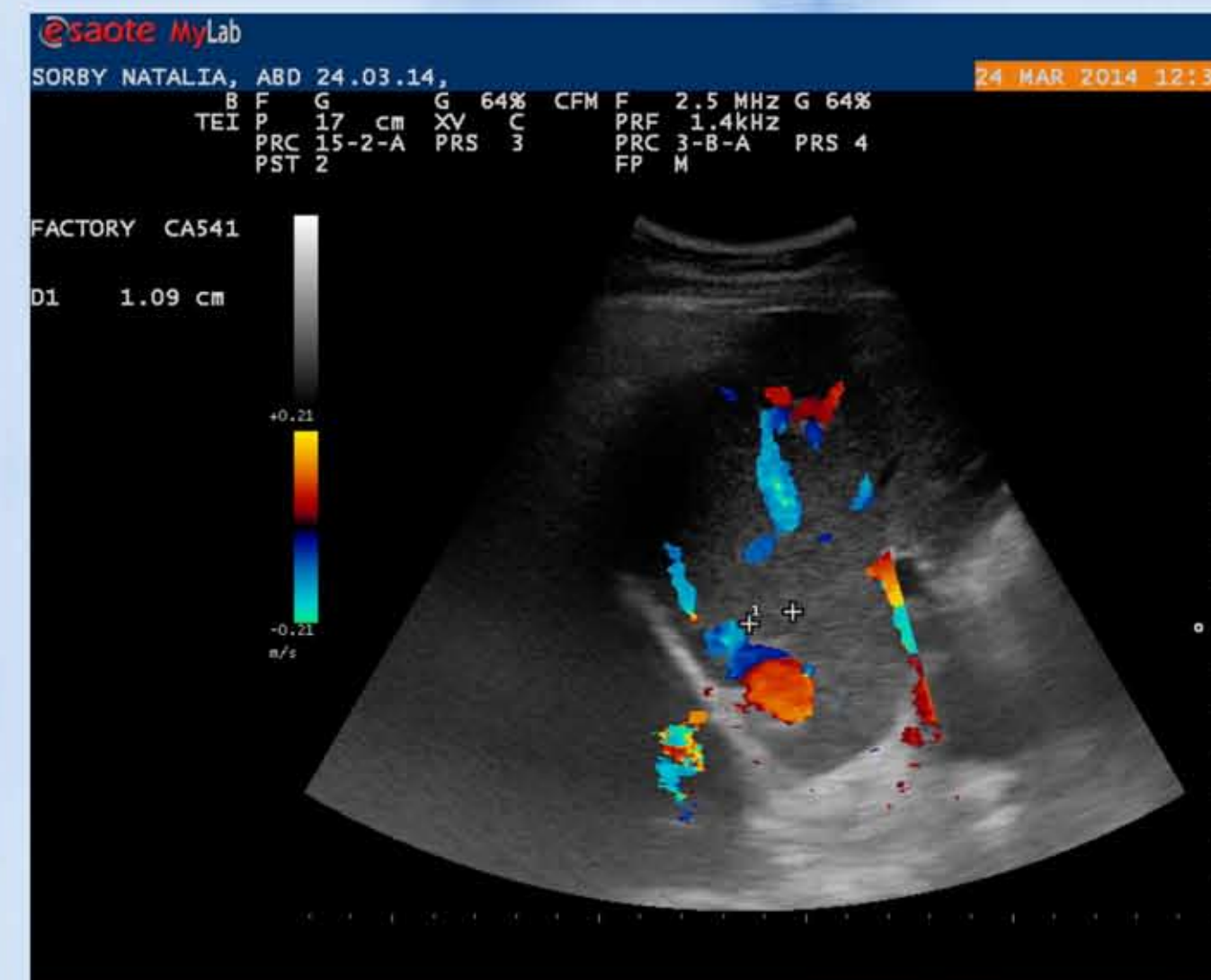
► We observed a change in volume from about 16.1 to 12.7 ml (-28%).

► 54-year-old female. **Metastatised lung cancer**. Ultrasonography of the liver and of the spleen was performed to assess modifications of the previously described metastases, following the integrative immunotherapy approach. We observed a change from 1.27 cm (liver) and 1.10 cm (spleen) to 1.08 and 0.90 cm, respectively. (-38% volume reduction liver. -45% spleen).

BEFORE treatment



AFTER treatment



BEFORE treatment



AFTER treatment

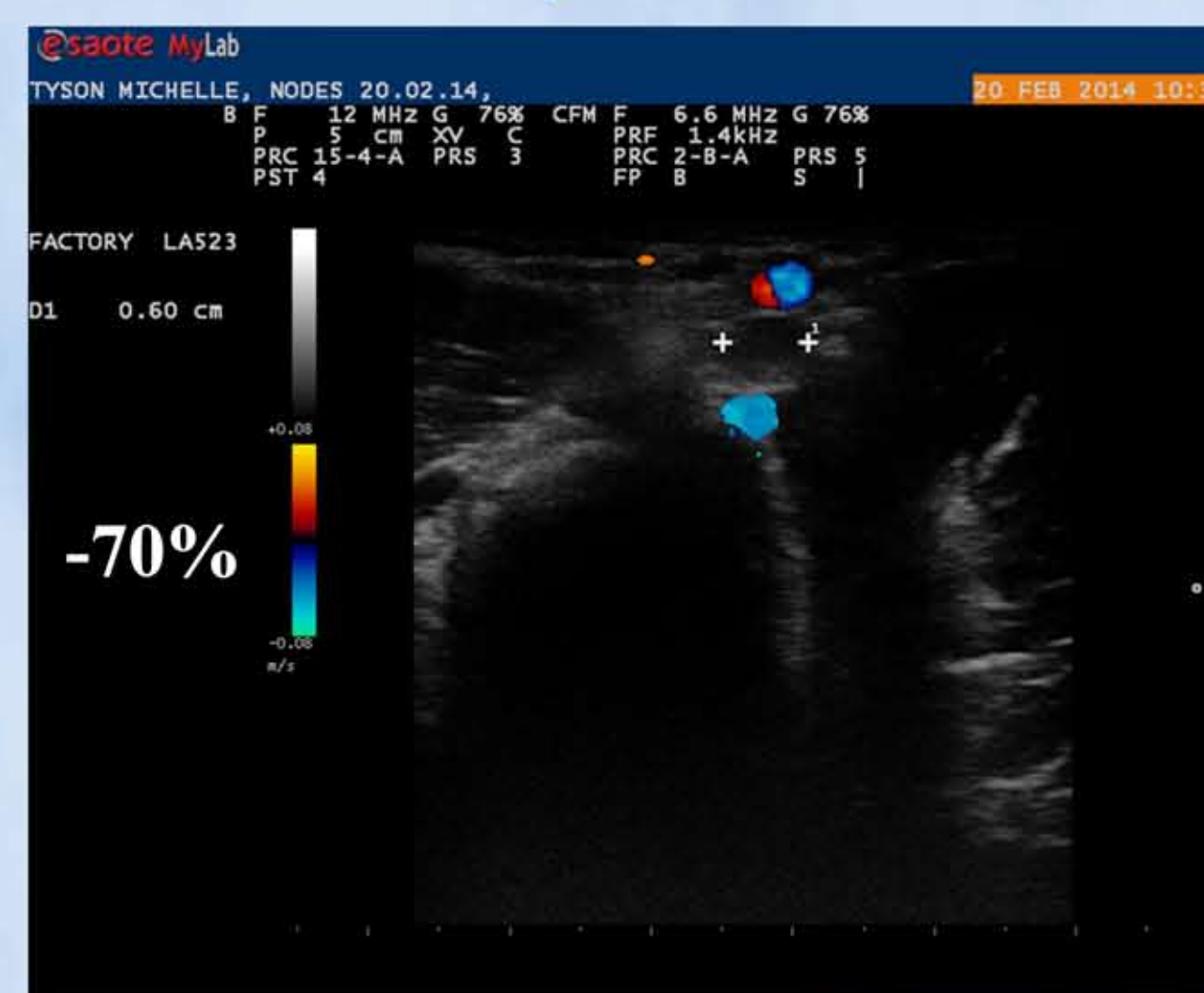


54-year-old female. Metastatised lung cancer. Ultrasonography of the spleen.

► 45-year-old female. Extensive breast cancer with axillary node involvement.

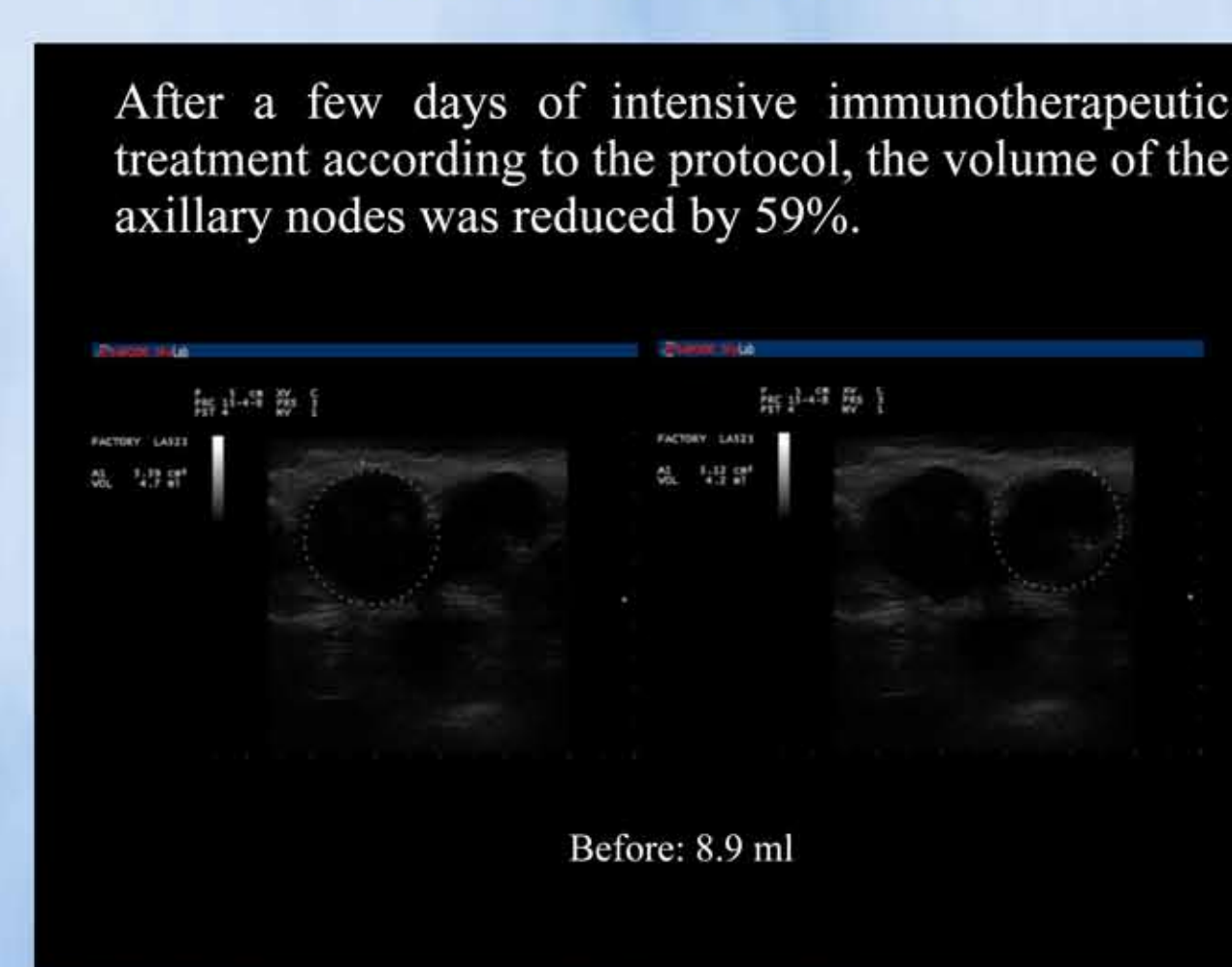


BEFORE treatment

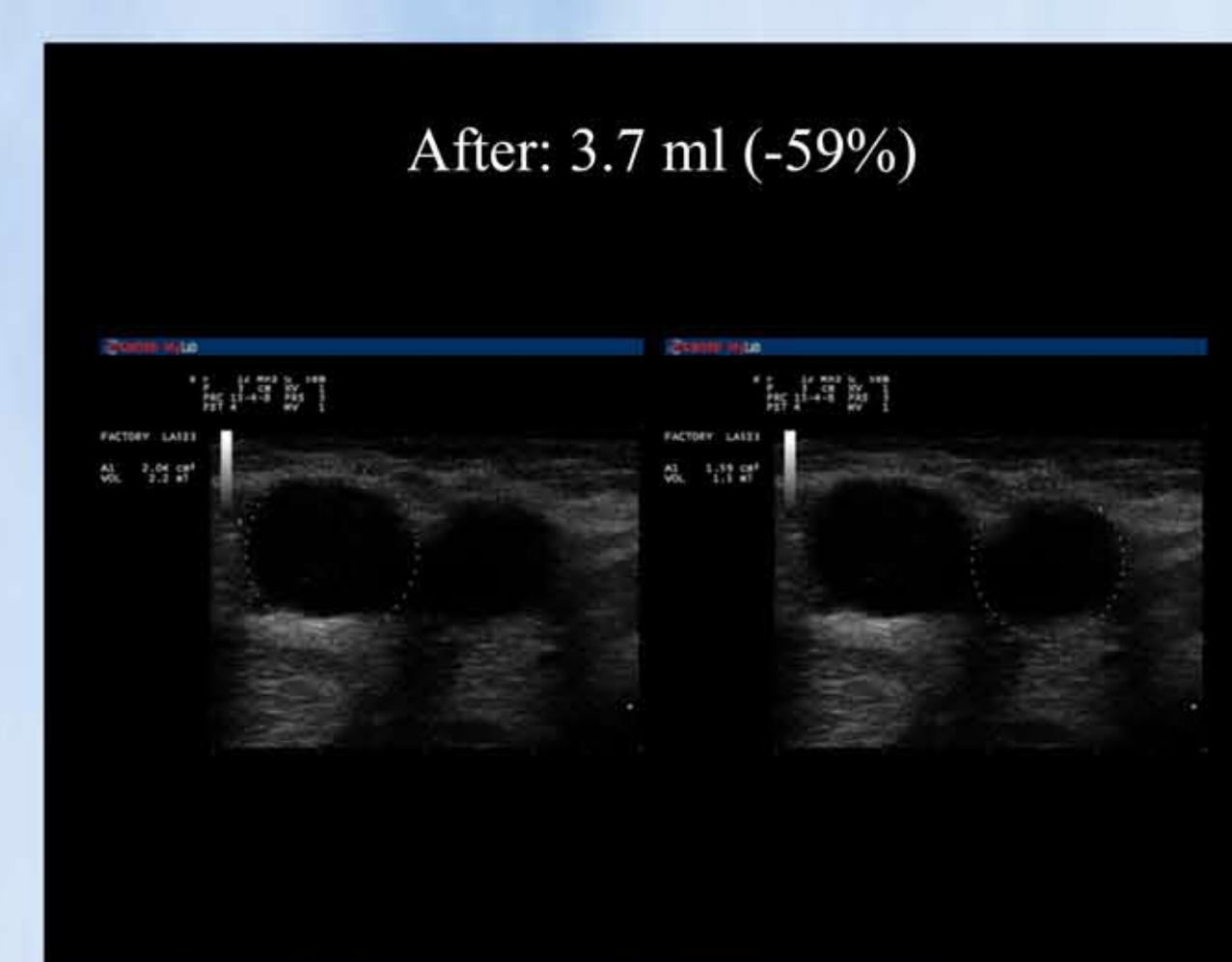


AFTER treatment

BEFORE treatment



AFTER treatment



► 61-year-old female. Very extensive **breast cancer** with severe lymphnodal involvement. The primary tumour comprised most if not all the breast and the Patient was labelled as **"inoperable/incurable"**.

► Thanks to the reduction of the volume of the primary tumour and nodes, the Patient became **"operable"**. She was successfully operated. The tumour was entirely removed.

CONCLUSIONS

- We are aware that the clinical cases reported here are heterogeneous and describe patients with different types of tumours at different stages.
- In most cases, patients had undergone a variety of conventional and complementary therapeutic approaches.
- In most cases, integrative immunotherapy was initiated at late stages of tumour progression.
- Since this is an open-label, non-controlled, retrospective analysis, caution must be employed when ascribing cause and effect to any treatment outcome.
- However, the response to integrative immunotherapy was robust and, even though any statistical analysis is inappropriate in such a heterogeneous recollection of clinical stories, the absence of adverse side effects and clinical improvement supported by objective evidences emerge evident.

ACKNOWLEDGEMENTS

► We wish to thank the Committees and the Patrons of the Conference for having accepted this study of ours. Quoting the words of the President of the SIICA 9th National Conference, we too **"firmly believe that the SIICA 9th National Conference in Florence will become for all of you an unforgettable event."**



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