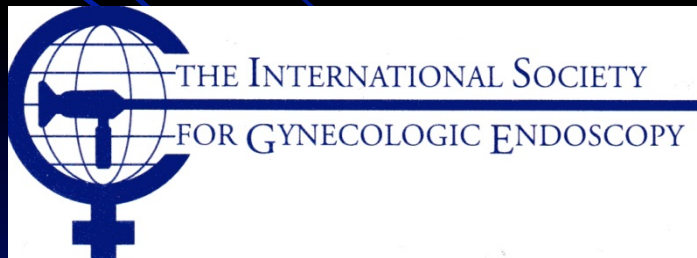


# ISGE PROSPECTIVE MULTICENTRE CLINICAL TRIAL ON RISK OF UNASPECTED LEIOMYOSARCOMA DURING LAPAROSCOPIC MYOMECTIONY OR HYSTERECTOMY

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Participants: Chuck Miller, Bruno van Herendael, Alfonso Rossetti, Alessandro Loddo, Matteo Saldari, Stefano Bettocchi, Giuseppe Florio



# BIOCHEMICAL EVALUATIONS: Total LDH and its isozymes

Both total LDH and LDH isoenzyme type 3 were elevated in all 10 patients with LMS

**Combining MRI and LDH serum levels: SP 100%, SE 100%, PPV 100%, PNV 100%, DA 100%**

MRI alone: SP 93.1%, SE 100%, PPV 52.6%, PNV 100%, DA 93.1%

- *Goto et al. International Journal of Gynecological Cancer 2002;12:354–61.*

# ULTRASOUND: LMS

Subjective semi quantitative assessment (vascular score) of the blood flow examined with directional PDI (Power Doppler Imaging)

A score of:

- 1 is given when no blood flow is found
- 2 is given when only minimal flow was detected
- 3 is given when moderate flow is present
- 4 is given when numerous vessels are present

The score for both central and peripheral region are combined with a maximum vascular score of 8

A high vascularity score ( $\geq 7$ ) is highly suspected

*Exacoustos C et al. 2007*

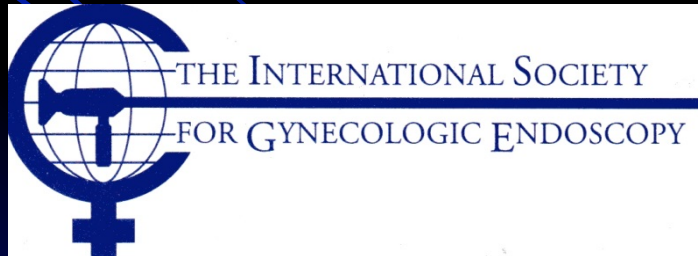
# MRI: DWI and ADC maps

- DWI is affected by random molecular motion and the image reflects the diffusion of hydrogen molecules, whereby high-intensity signal is evident in places with reduced diffusion\*
- DWI can also provide quantitative measurement of apparent diffusion coefficient (ADC) values, which are considered to be influenced by the nuclear-to-cytoplasm ratio and cellular density in solid tissues.
- **Increased DWI signal intensity and decreased ADC values of malignant tumors** compared with normal tissues or benign lesions have been previously reported for various organs\*\*

*Sato K et al. 2014*  
*Fujii S et al. 2008*

# AIM OF THE STUDY

- To provide a preoperative diagnostic flowchart in order to detect all occult LMS before surgery for uterine fibroids
- To evaluate US and MRI performance in the differentiation between uterine LM and LMS



# CLINICAL EVALUATION

- **GYNECOLOGICAL EVALUATIONS:**

Recent PAP smear

**HYSTEROSCOPY AND ENDOMETRIAL BIOPSY** in all the patients with abnormal uterine bleeding and in all the patients scheduled for SCH

- **BIOCHEMICAL EVALUATIONS: TOTAL LDH and its ISOZYMES**

# PARTICIPANT SELECTION/ ELEGIBILITY CRITERIA

## Inclusion criteria

**At least one of the following *CLINICAL CRITERIA*:**

- Age: > 35 years
- Postmenopausal status
- Postmenopausal bleeding
- Rapid fibroid/uterine growth ( $\geq 20\%$  in 6 months)
- Unique fibroid
- Certain treatment (tamoxifene or pelvic radiation)
- Hereditary conditions (Lynch syndrome or hereditary leiomyomatosis and renal cell cancer)
- High LDH blood value

# PARTICIPANT SELECTION/ ELEGIBILITY CRITERIA

## Inclusion criteria

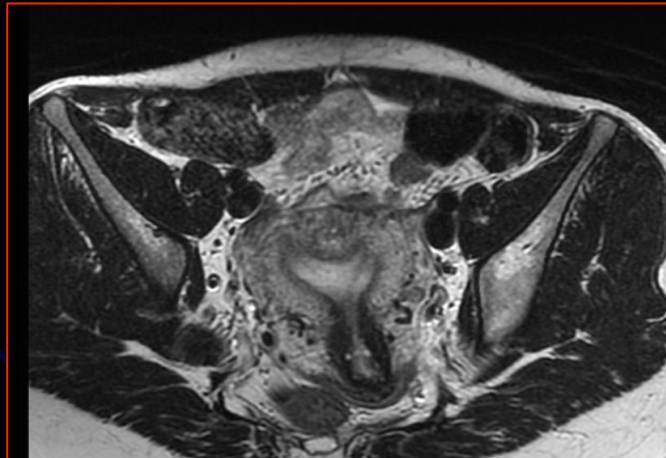
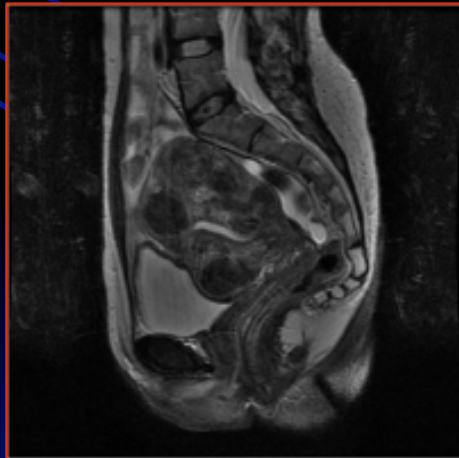
At least one of the following **US CRITERIA**:

- Presence of central vascularization
- Distribution of tumoral vascularization: high vascularity score ( $\geq 7$ )
- Inhomogeneous echo pattern with inhomogeneous and bizarre internal echo pattern
- Necrotic, cystic or hemorrhagic aspects
- Ill-defined and irregular margins
- Lack of acoustic shadowing
- Abnormal or not seen endometrium



# PARTICIPANT SELECTION/ ELEGIBILITY CRITERIA

Patients with at least one of the ***CLINICAL CRITERIA*** and one of the ***US CRITERIA*** undergo MRI examination before surgery



# MRI PROTOCOL

- Axial and sagittal T1-weighted images with and without FS
- Axial, coronal and sagittal T2-weighted images with and without FS
- Axial and sagittal DWI images and corresponding ADC maps
- Contrast-enhanced T1-weighted images

# IMAGING: MRI

## **At least three of the following MRI CONVENTIONAL CRITERIA:**

- irregular margins
- presence of intratumoral haemorrhage
- presence of intra-tumoral cystic alterations
- heterogeneous enhancement
- intermediate or high T2 signal intensity
- intermediate or high T1 signal intensity
- enhanced areas
- T2-weighted signal heterogeneity
- T1-weighted signal heterogeneity
- endometrial stripe: unidentifiable, thickened or with intracavitary process
- ascites

## **At least one of the following MALIGNANT criteria:**

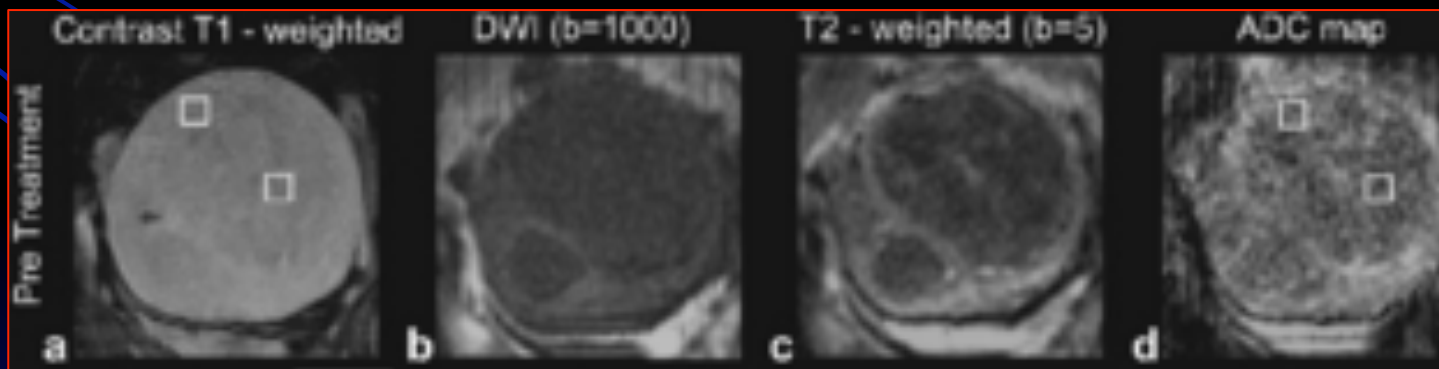
- lymphadenopathy
- invasion of the mass into the bladder, rectum, pelvic side walls or other structures
- peritoneal implants

# MRI CRITERIA: DWI and ADC maps

- High b1,000-weighted signal

AND

- Mean ADC at  $1.23 \times 10^{-3} \text{ mm}^2/\text{s}$  or less



# PREOPERATIVE DIAGNOSTIC FLOW-CHART

AT LEAST ONE CLINICAL CRITERIA, ONE US CRITERIA,  
or HIGH LEVELS OF LDH ISOENZYMES

*yes*

*no*

HIGH RISK GROUP

LOW RISK GROUP

MRI

At least three conventional MRI criteria OR one malignant MRI criteria  
AND/OR  
High b1,000-weighted signal with Mean ADC at  $1.23 \times 10^{-3} \text{ mm}^2/\text{s}$  or less

*yes*

*no*

HIGH RISK GROUP

LOW RISK GROUP