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CROSS-SECTIONAL STUDY ON LOWER URINARY TRACT SYMPTOMS AND COMPLICATIONS AND THEIR HRQL IMPACT IN A COHORT OF PATIENTS WITH MULTIPLE SCLEROSIS USING STANDARDIZED QUESTIONNAIRES.

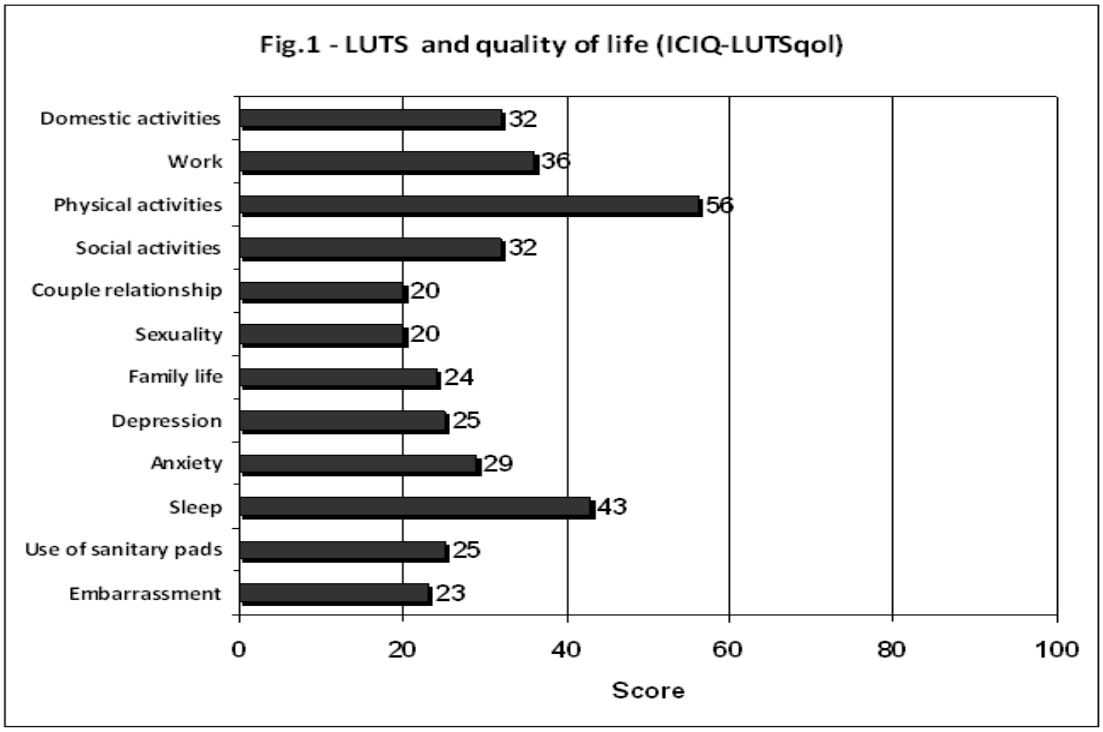
Hypothesis / aims of study
Lower urinary tract symptoms (LUTS) and urinary tract complications have been reported to be common in patients with multiple sclerosis (MS) [1,2]. We aimed to determinate the prevalence of LUTS and urinary complications in a cohort of patients diagnosed with MS and followed at our MS referral multidisiplinary center. The impact on HRQL and correlations between LUTS and disease characteristics were also investigated.

Study design, materials and methods
An observational, cross-sectional study was conducted including 125 consecutive patients, 56 males and 69 females, mean age 46.2 (SD 12.8; range 22-79 years), with clinical diagnosis of MS that underwent a comprehensive neurological and urological evaluation. Patients were divided into three clinical groups based on the course of disease: primary progressive (MSPP), relapsing–remitting (MSRR) and secondary progressive (MSSP). LUTS and urinary complications were investigated by a structured urologic interview and two standardized, self-administered questionnaires: ICIQ-MLUTS for male patients and ICIQ-FLUTS for female patients. The impact of LUTS on patients' HRQL was evaluated by using the ICIQ-LUTSqol questionnaire. Patients were evaluated for overall disability using the Expanded Disability Status Scale (EDSS). Lesion sites were determined by mean of magnetic resonance imaging (MRI).
We used SPSS 13.0 for Windows for statistical analysis. Chi-square tests were used to evaluate the measure of association. Spearman's rank correlation was used to describe the dependence between two variables. A multivariate regression analysis has been performed using patients and diseases characteristics as independent variables and complaint of LUTS (yes/no) as dependent variable. A P-value <0,05 was considered statistically significant.

Results
Eighty out of 125 (64%) of patients complained of at least one LUTS without no significant difference between sexes (62.5% of male patients and 65% of female patients). LUTS were present in 43% of patients in the early stage of disease. Twenty-nine percent of patients had pure storage LUTS, 20% had pure voiding LUTS and 51% had mixed LUTS. Urgency was the most frequent storage-phase LUTS (69%), followed by urgency urinary incontinence (56%), stress urinary incontinence (38%), nocturia (34%) and frequency (25%). Sense of incomplete voiding (58%) and intermitted voiding (58%) were the most frequent voiding-phase LUTS, followed by hesitancy (53%) and straining (45%).
In 36% of patients with LUTS occurred urinary complications: the most frequent were infections of LUT (82%), followed by pielonefritis (7%), acute urinary retention (7%) and ureterolithiasis (4%). No one had kidney failure.
No significant correlation was found between LUTS and lesion sites at MRI.
Seventy-nine patients (62%) had MSRR, 33 (27%) had MSSP and 13 (10%) had MSPP. We found a statistically significant correlation between course of disease and LUTS that were more frequent in MSSP (97%) and MSPP (91%) patients than in MSRR (45%) patients.
Mean duration of disease was 12.1 years (Range:1-42). A direct correlation was observed between duration of disease and complaint of LUTS.
Mean EDSS score was 3.2 (range: 0-8) A direct correlation was observed between EDSS score and complaints of LUTS. The average EDSS score was 4.24 (SD=2) in patients referring LUTS and 1.40 (SD=1.2) in patients without LUTS.
Fig.1 displays the impact on the different aspects of HRQL as measured by ICIQ-LUTSqol questionnaire (scores reported on a 0-100 scale, higher score meaning greater HRQL impact) . Physical activities and sleep were the most affected domains of HRQL.
As consequence of LUTS, 40% of patients reported a decrease in physical activities, 38% an impairment in work activities, 37% a difficult sleeping, 36% decreased social activities, 34% travelling problems. Twenty-five % and 20% of patients reported anxiety and depression for their urinary problems, respectively. The average score for the impact of urinary disorders on patients' daily life was 36.2 (SD= 36). A worse HRQL was observed in patients with mixed symptoms compared to patients with pure storage or pure voiding symptoms ($p<0.05$).

Interpretation of results
LUTS were highly prevalent in MS patients with no difference between genders. Most patients reported mixed (storage-voiding) symptoms. Age, and characteristics of the neurological disease such as course, duration and EDSS score were associated with complaint of LUTS in multivariate analysis. LUT infections were frequent but upper urinary tract complications were uncommon. LUTS were associated to a significant impact on HRQL of patients with MS with no difference between genders.

Concluding message
Although severe urologic complications are uncommon, LUTS should be always investigated in patients with MS because of their significant prevalence and impact on HRQL, especially on account of the several therapeutic modalities today available for LUT dysfunctions and of the longer time that MS patients remain with mild neurological symtpoms with the advent of disease-modifying treatments.



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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Observational study using data gathered by mean of tools used in standard practice in our center.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**