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Original article:

The first experience with a mini-rating scale for the assessment of sexual dysfunction and life-satisfaction in depressed patients in the practice

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ABSTRACT

Even though many scales for the assessment of sexual dysfunction have been recently developed, most of them are suitable rather for the research purpose in clinical trials than to routine interviews in a daily, private practice. We report here the first experience with a simple, semi-quantitative scale for parallel assessment of sexual dysfunction and life-satisfaction (considered to globally reflect the quality of life), which was tested in depressed patients treated in the psychiatric, private practice setting. A combined Sexual Dysfunction(SD-S) and Life-Satisfaction Scale (LS-S), was constructed based on previous interviews with patients. Both consisted of 4-items, assumed to represent core elements of sexual function and individual well-being. The scales were applied to depressed patients treated with any of the SSRIs or with moclobemide, a reversible and selective MAO-A inhibitor. These two treatments were selected for testing the scales because it is known that SSRIs can induce or exacerbate them and moclobemide does not seem to affect them. The selection of treatment modality in this study was, however, entirely at the discretion of the physician. The assessments were done during 3 visits (at baseline, after 2 months and after 4 months). The results of this exploratory trial, testing the applicability, acceptance and utility of a combined mini- SD-S- and LS-S- scale, in 62 depressed patients, showed that the scale: a) was simple to use and well accepted by physicians and patients, b) was a suitable instrument for the practicing physician to control the success of the treatment and c) was sensitively assessing the presence and severity of sexual dysfunction.

Key words: sexual dysfunction, life-satisfaction, sexual dysfunction scale, depression, SSRI, IMAO-A, moclobemide

INTRODUCTION

There is no controversy today about the considerable impact of sexual dysfunction on the well being and overall satisfaction with life of each individual. Impaired sexual

functioning may compromise the family life and partnerships and cause problems of compliance with therapies inducing sexual dysfunction. Specifically, in depressed patients, sexual dysfunction emerging during treatment represent a problem. In an

epidemiological survey of over 6000 depressed patients, 75% stated that having a good sexual life is fairly or very important to them (Baldwin and Thomas 1996). In another more recent survey >95% of depressed patients, both men and women, considered sexual activity as an important factor of their life quality when they are well and in remission (D. Baier personal communication). Further, patient's satisfaction with treatment is an increasingly important criterion in judging the appropriateness of the selected treatment and may decisively influence the choice of any drug for an outpatient in the practitioners settings.

Systematic assessment and rough quantification of sexual dysfunction and patient's satisfaction with the treatment are, to the best of our knowledge, seldom if at all, a part of a routine interview in the general practice (GP). They are not common even in the psychiatric practices. In the recent study of National DMDA (Depressive, Manic- Depressive Association) in USA, 69% of physicians stated that they mention possible sexual dysfunction problems to patients. But, more than 40% of patients negated any questioning of their sexual life by the physician. In the practice, however, particularly women, rarely spontaneously report sexual problems and the physicians frequently neglect to consider the impact that they may have on the success of treatment and patient recovery. The exploration of sexual life and of the willingness for tolerance of possible treatment caused dysfunction, can, however, provide important information about the appropriateness of the drug to be selected for the therapy. Further, systematic and accurate assessment of sexual functions during the therapy would, for instance, permit the physician to better distinguish the depression-associated loss of libido from drug-induced dysfunction. It would in

addition help to prevent the non-compliance with the treatment with all its consequences. Even though several scales for the assessment of sexual function have been currently developed (McGauhey et al. 1999), most of them are suitable rather to the research purposes than to everyday clinical practice. Many of them are either too lengthy to be used routinely, or are intrusive, particularly for the female patient. They are also not always constructed to suit to traditional attitude and cultural background of every population. Further, they are not always sufficiently sensitive to treatment-induced changes and, finally, they mostly fail to control for patient satisfaction with the outcome. This last point is not an unimportant factor of good compliance. At least in Switzerland, none of the sexual function scales has found its systematic use in the general practice or private psychiatric practices. We felt, therefore, that there is still a need for a simple, users friendly instrument that will provide an information to the practicing physician about the patient's sexual life and life satisfaction in an accurate and easy to follow form.

We report here our first experience with a semi-quantitative, mini- scale for parallel assessment of sexuality and life -satisfaction in depressed patients. The scale was constructed to specifically suit a routine check during interviews of patients in the general or psychiatric private practices. It focused on the core elements of sexual function and on parameters generally considered to be relevant for the overall well-being e.g. satisfaction with life of an individual. The items of the scale emerged as important and easy to understand for the even uneducated patient during preliminary, free and unstructured, interviews with depressed patients attending practicing psychiatrists.

We have tested the applicability of the scale in depressed outpatients under treatment with SSRIs and moclobemide, a reversible

and selective MAO-A inhibitor. Sexual dysfunction during therapy with SSRIs is common and well known. In a recent review Hirschfield (1999) refers to an incidence range of 4-75%. Based on studies with more systematic assessment, Modell et al. (1997) estimated that approximately ¾ of treated patients experience one or more sexual problems when taking SSRIs. In contrast, moclobemide seems to be devoid of own deleterious effects on sexual function (Philipp et al. 1993, Philipp et al. 1999, Philipp et al. 2000).

MATERIALS AND METHODS

Design of the study

This was an open, prospective, naturalistic (observational), non-interventional study carried out in 3 psychiatric private practices in a French-speaking part of Switzerland. Patients (male and female aged >18 years) were included into the study if they presented symptoms of chronic depression and were in need of long-term treatment with antidepressants. The selection of treatment modality (any SSRIs or moclobemide), as well as of the dosing regimen, was entirely at the discretion of the investigator and was guided by his clinical experience and routine only. Nosological classification of the underlying depressive disorder was not considered as an *a priori* inclusion/exclusion criterion. But, patients were excluded from the study if they presented any other mental condition not primarily diagnosed as depression by ICD.10 criteria. The study period was 4 months.

No specific restrictions of the co-medication were required, but the use of benzodiazepines was discouraged.

Prior to the formal start of the assessments, patients were informed by the physician that their sexual behaviour will be specifically questioned during the a limited period of treatment and were instructed how to understand the questions.

Assessments

Besides general information about the patient, history of depression and previous treatments, following assessments were done at the beginning of the trial (baseline, Visit 1), after 2 months (Visit 2) and 4 months (Visit 3) when the collection of data was formally terminated:

- **Life-Satisfaction (LS-S)**

The life-satisfaction scale (LS-S) was devised to globally record affective and performance-oriented life aspects by physician's interview. It consisted of 4 items considered to be important for the patient's well being and satisfaction with current life: 1) Performance (work efficiency, pleasure, satisfaction with self), 2) Leisure (hobbies, social life, relationship with family, relatives, others), 3) Sexuality (enjoyment, interest, satisfaction) and 4) Global satisfaction with present state. During the interview the physician asked the patient to appraise the importance of each item and the degree of his/her satisfaction with it. One to four points could be allocated to each item. For the "importance" the gradation was as follows: 1= not important, 2=of little importance, 3= quite important, 4=very important. Satisfaction scores were: 1 = not at all satisfied 2= hardly satisfied 3= satisfied, 4= very satisfied. Maximum total score for life-satisfaction was 16.

- **Sexual Dysfunction (SD-S)**

Sexual dysfunction scale (SD-S) consisted of 4 main items, which were unrelated to the gender: 1) libido 2) sexual arousal 3) orgasm and 4) frequency of desire for sexual activity. For men, the item 5) "erection/ejaculation" was rated in addition. The items were rated as present (yes) or absent (no) and, if present, by severity from "slight"=1, "moderate"=2 to "severe"=3. Maximum dysfunction score for both female and male patients was 12 and for men 15.

The scales are presented in the Annex.

- **Severity of depression**

In order to control for changes of depressive state, severity of depression was rated by means of the conventional Clinical Global Impression (CGI) 6- points scale (0= none, 1=borderline, 2=mild, 3= moderate, 4= severe, 5= very severe). No other specific assessments of depression were included because the assessment of the antidepressant efficacy of treatments was not the objective of the study.

At each visit (Visit 1 = Baseline, Visit 2 = after 2 months, Visit 3=after 4 months) the prescribed medication and the co-medication were recorded and the compliance of the patients with treatment verbally inquired.

Prior to the start of the study an investigators meeting was held in order to ascertain and adjust the interview (semi-structured) technique about sexual functions and the assessment attitudes of the study participants. The investigators were instructed to ask ten standard questions (see Annex) at the beginning of the interview and before starting more specific

exploration of patient's problems and completion of the questionnaires.

- **Analysis of the results**

Since the primary aim of the study was not to validate the scale, but to first test its acceptance and applicability in the practice, the statistics applied was only explorative. Means and standard deviations of demographic variables were calculated and, because of the ordinal quality of scales, Box-Whisker Plots showing median, quartiles and minimum/maximum values were used to assess scale values and changes. In order, however, to get an estimate of the magnitude of assessed changes between the visits, non-parametric, paired Wilcoxon-test for dependent samples; Friedman's ANOVA as well as Mann-Whitney U-test were applied, if appropriate.

RESULTS

The results of interviews with a total of 62 patients, completing 4 months of antidepressant treatment, were available for the analysis. Demographic characteristics of the patient population are given in Table 1.

Table 1: Demographic characteristics of the study population

Treatment	N	AGE Mean ± SD	F %	M %
Moclobemide	28	46.1±12.4	42.9	57.1
SSRIs	34	43.1±11.3	67.6	32.4
All	68	44.2±11.7	59.9	41.1

The patient groups were fairly balanced with respect to the number of patients under SSRIs (N=34) and moclobemide (N=28). There was however significant difference in the distribution of gender between the groups in that there were significantly more females than males in the SSRIs group (67% vs. 32%) whereas in the moclobemide group the number of males dominated (57%

vs. 41%). This sampling error had to be accounted for in the analysis of the results. Because this gender differences could influence, particularly the results related to sexual functions, a separate analysis of the sexual function variables in males and females was performed.

SSRIs used for the treatment were paroxetine (n=9), fluvoxamine (n=3), fluoxetine (n=8) and citalopram (n=12) at usual, recommended, fixed therapeutic doses. The doses of moclobemide (n=28) were in the range between 150 to 450 mg/daily.

With respect to the severity of depression there was no significant difference between the SSRIs and moclobemide groups at baseline. The CGI median values were 2.7 and 3.2 respectively. There was however a larger variation (25-75% quartiles II-III) in the SSRIs group. In the SSRIs group the quartiles II-III values varied between 1-4, whereas in the moclobemide group they were between 3-4. Strictly, this means that there were more severe cases in the

moclobemide than in the SSRIs group (in which the female population dominated).

There were no significant overall differences in other variables (LS, sexual dysfunction) between the groups. Nevertheless, the analysis of sexual dysfunction by gender revealed larger variance and lower severity of dysfunction in the SSRIs treated female patients when compared to the SSRIs treated males or to the male and female moclobemide groups.

Life-satisfaction (LS-S)

The life-satisfaction changed during the treatment. There was a clear shift to the greater satisfaction toward the end of study and the difference between initial and end LS-S total score in drug- groups proved to be highly significant (Table 2).

Table 2: Changes of LS- scores during treatment

Treatment	N	Baseline Mean ±SD	Visit 2 Mean ±SD	Visit 3 Mean ±SD
Moclobemide	28	5.9± 2.94	6.7 ± 3.17 ¹	7.8 ± 3.93 ¹
SSRIs	34	6.8 ± 3.53	7.8 ± 3.70	8.5 ± 3.75 ²

¹p< 0.003 vs baseline, ²p< 0.002 vs baseline (Wilcoxon-paired test)

There was no difference between the treatments with respect to achieved satisfaction at the end of the trial, but the variability of the response to moclobemide (revealed by Whisker-Box Plot quartiles II-III: 25-75%) was much smaller than that to SSRIs. The judgement of importance of each life-satisfaction item showed no variations and changes during any treatment. Each item of the scale was consequently scored as very important by each patient.

Sexual Dysfunction Scale (SD-S)

The analysis of the questionnaires (all patients) revealed overall higher severity and higher variability of the total scores for sexual dysfunction in the SSRIs group (females and males) than in the moclobemide group. But, the bias of this result due to the imbalance of genders in the treatment groups had to be considered and therefore further analysis by gender was of interest. It revealed somewhat lower severity larger variability of the SD- scores in the SSRI female patients over time than in males (quartiles II and III, 25-75%, Figure 1 and 2).

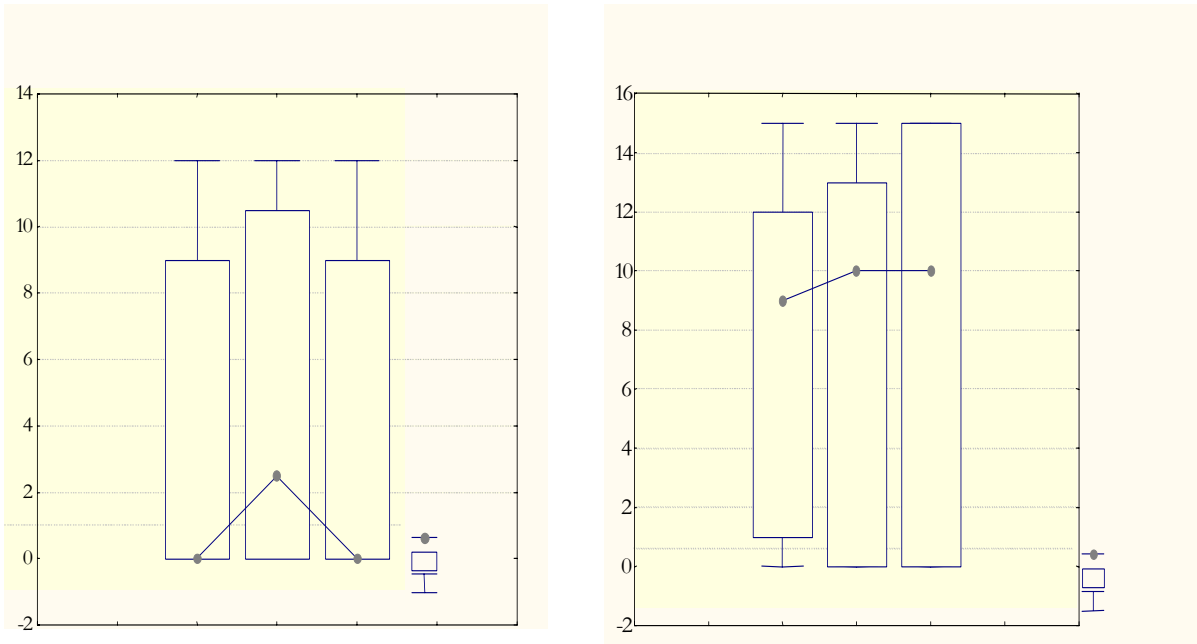


Figure 1(left) and 2(right): Each bar represents the Box- Whisker plots 25-75% quartiles with minimum and maximum values of sexual dysfunction scores in SSRIs-treated female (Figure 1) and male (Figure 2) patients. Each point at the curves represents the median SD score at visits 1-3

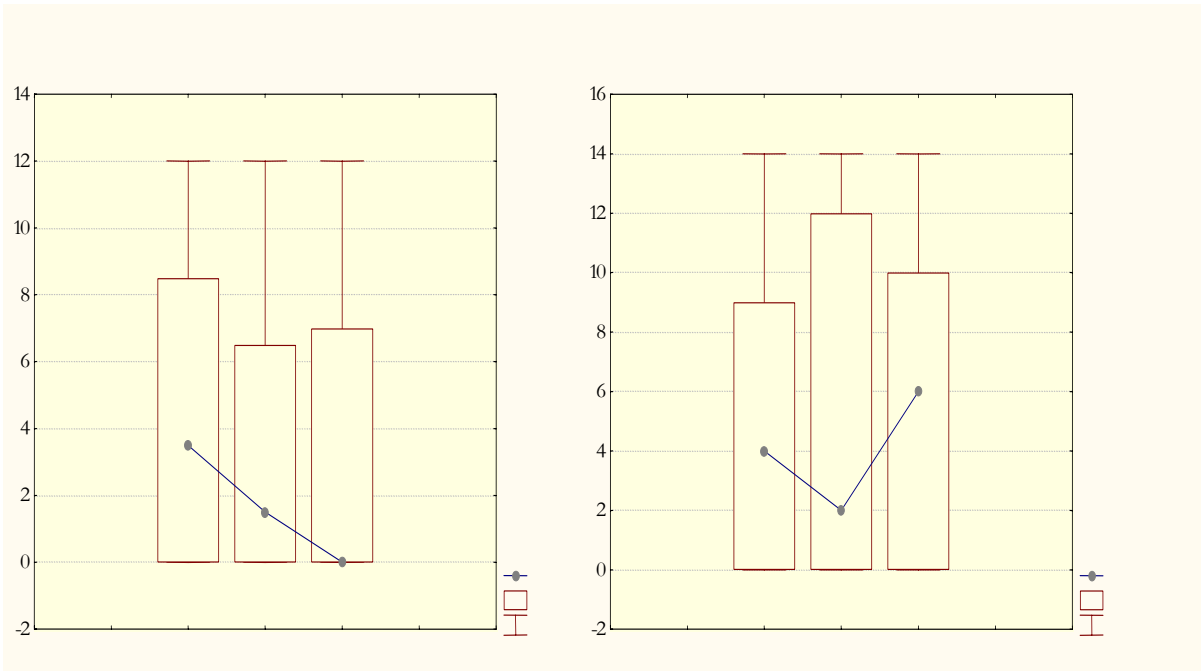
The analysis of results collected in the moclobemide group revealed somehow opposite gender-related effects (Figure 3 and 4). In female patients median SD scores between the visits 1 to 3 dropped visibly, although the difference failed to reach statistical significance at 5% level (Friedman's ANOVA $\text{Chi}^2 = 0.636$, $p < 0.73$). In male patients the median scores varied between the visits without a visible trend in either direction. These variations were not significant (Visit 1-3: Friedman's ANOVA $\text{Chi}^2 = 0.560$, $p < 0.76$).

Severity of depression

There was a sustained improvement of depression in the drug treated patients, which was reflected in the significant drop of the severity scores from one visit to the other (Table 3). There was no overall significant difference between the SSRIs and moclobemide with respect to the efficacy of treatment.

Safety of treatments

All treatments were well tolerated. In none of the patients the treatment had to be discontinued because of safety reasons.



Figures 3(left) and 4(right): Each bar represents the Whisker Box plot (quartiles 25-75%) and minimum- maximum values of sexual dysfunction score in female (Figure 3) and male (Figure 4) patients treated with moclobemide at each visit (visit 1-3). Each point on the curves represents the median score of sexual dysfunction at each visit.

Table 3: Changes of the severity of depression (CGI) during treatment

Treatment	N	Baseline Mean±SD	Visit 2 Mean±SD	Visit 3 Mean±SD
Moclobemide	28	3.2±0.61	2.5±0.96	1.9±1.39***
SSRIs	34	2.7±1.26	2.3±1.12	1.5±1.36***

*** p<0.001 vs. Baseline (Wilcoxon paired test)

DISCUSSION

The main objective of this study was to explore the applicability of a simple, mini-rating scale for parallel assessment of sexual dysfunction (SD-S) and life-satisfaction (LS-S). These scales were designed with the purpose to suit routine use in the private practice setting. The study was guided by the assumption that: a) (feasibility) systematic assessment of only core-aspects of sexual functioning with simple, non-intrusive, mini- scale might still provide sufficient guidance to physician about the patient's sexual problems during drug treatment; b) (appropriateness and sensitivity) that such instruments can

adequately measure the magnitude of changes during the treatment and, perhaps, c) (discriminative quality) be appropriate for the assessment of drug-drug differences.

The core items of our LS- scale were extracted from the English versions of various, but widely used QoL scales (Bech 1993), but the selection of items was primarily guided by clinical experience of the investigators with preceding interviews.

The sexual dysfunction scale was principally similar to the questionnaire proposed and used by Philipp et al. (1999), but its elements (libido, sexual arousal, orgasm, frequency of the desire for sexual

contacts) are also almost consistently used in other scales. In constructing the scale we intended to make it independent of the gender, but, in retrospect, we found that it was a failure not to introduce the item "vaginal lubrication" for female patients. Based on the experience from another study (Delini-Stula et al. 2003), we feel that this is an important parameter indicating the level of physical sexual arousal in women. We do intend therefore to revise the scale and introduce this item in the next version.

In the LS-scale the rating of 4 items, assumed to globally reflect patient's perception of the current well-being, were introduced primarily with the intention to have another dimension of the evolution of the patient's state during treatment. Indeed, in parallel with decreasing severity of depression, the assessment of the patient satisfaction with life dramatically and highly significantly increased. The measure of life satisfaction appeared therefore to be a very sensitive and valuable supportive evidence of the therapy success. Our data, however, were not suitable for a particular analysis of the relationship between the parameters of life-satisfaction and sexual dysfunction, which would certainly be of interest.

The analysis of the results showed that the presence and severity of sexual dysfunction in our population was reflected in the changes of the item scores during the trial. The changes varied in dependence of the drugs and genders. This variability might have had different reasons, but, importantly, the direction of changes in SD did not seem to be parallel to the improvement of depression. It is to note also, that in none of the treatment groups the changes in SD score have attained significance level, not even in the moclobemide treated female patients, in spite of the visibly consistent decrease of the severity scores between the visits. But, we consider here the significance or lack of significance of the changes during the treatment as meaningless for correct

interpretation of drug effects on sexual functions. As stressed before, the study was not fully controlled, individual drug treatments were not identical, and the gender subgroup samples too small to cope with individual variability. The data provide however an important argument in favour of the applicability of the scale, since they demonstrate that it was possible to measure the presence of sexual dysfunction and individual changes of their severity during the treatment.

The assessment of SD revealed gender-related differences in response to drug treatments. Globally, in males sexual dysfunction persisted under both drugs. In female patients there was visible improvement of SD under moclobemide treatment, indicated by rather large and sustained drop of median severity scores from one visit to the other. This was, however, a very small sample and various errors (sampling error, measurement errors, item (mis)interpretation) can account for the lack of statistical significance of this result. We are not aware of specific gender-related studies of moclobemide effects on sexual dysfunction. It is, nevertheless, interesting that in a comparative study of moclobemide versus doxepine performed by Philipp et al. (1993), in which the majority of patients were females, group comparison showed, by identical antidepressant efficacy, higher degree of improvement of sexual dysfunction under moclobemide than doxepine. Therefore, the effect of moclobemide that we have observed in our study is perhaps worth further exploration.

Irrespectively of the drug-related findings and limits of their interpretation, our combined mini-scale proved to be simple and user-friendly. It provided sufficient information to practicing physician in that: a) it accounted for individual changes during treatment in the form that b) permitted an adequate control of the treatment effects. In particular, the questioning was very well accepted and

easy to understand by patients. The only parameter of the scale, which in our study proved to be obsolete, was the rating of the importance of individual LS items. All the aspects of daily life were for our patient population of constant importance and this judgement was not influenced by patient's illness.

In conclusion, we feel that the findings of this study, exploring the applicability of combined, mini-, semi-quantitative scale for

the assessment of sexual functioning and life-satisfaction in depressed out-patients, encourage further testing and validation of its applicability in the practice.

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ANNEX

Life Satisfaction (LS-S) and Sexual Dysfunction Scale (SD-S)

Life- Satisfaction Scale (LS-S)*

	Satisfaction				Importance			
	High	Moderate	Low	Very low	None	Low	Moderate	High
<ul style="list-style-type: none"> ▪ Activities and performance (working efficacy, pleasure and satisfaction with self) 	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
<ul style="list-style-type: none"> ▪ Free-time activities (hobbies, social life and family relationships) 	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
<ul style="list-style-type: none"> ▪ Sexual life and enjoyment (pleasure and interest, desire) 	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
<ul style="list-style-type: none"> ▪ Global satisfaction (with actual life) 	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
	Total score _____				Total score _____			

* Translation of the French version

Sexual Dysfunction Scale (SD-S)*

Do you have at present any problems with your sexual life and if yes how severe are they?					
			<u>Severity</u> (degree of impairment)		
			1=mild, 2= moderate, 3= severe		
1. Libido (sexual drive, desire)	No	<input type="checkbox"/>	1	2	3
		If yes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Yes	<input type="checkbox"/>			
▪ 2. Initiation of sexual act (ease of sexual arousal)	No	<input type="checkbox"/>	1	2	3
	Yes	<input type="checkbox"/>	If yes	<input type="checkbox"/>	<input type="checkbox"/>
▪ 3. Orgasm (ease of achievement)	No	<input type="checkbox"/>	1	2	3
	Yes	<input type="checkbox"/>	If yes	<input type="checkbox"/>	<input type="checkbox"/>
▪ 4. Frequency of desire for sexual activity (frequently, rarely , not at all)	No	<input type="checkbox"/>	1	2	3
	Yes	<input type="checkbox"/>	If yes	<input type="checkbox"/>	<input type="checkbox"/>
TOTAL SCORE (males & females)					
For men only	No		1	2	3
▪ 5. Erection/ejaculation (ease, maintenance/delayed, premature)	Yes		If yes	<input type="checkbox"/>	<input type="checkbox"/>
TOTAL SCORE men					

*Translation of the French version

Instructions for the use of Scale

LS-S: In a collaborative interview patient is invited to rate her/his satisfaction with life with respect to the overall satisfaction and importance (attributed to performance, leisure activities and sexual life, global life satisfaction) during the past week. A score from 1 to 4 is used to define the degree of life-satisfaction and importance of the item.

SF-S: After explaining the aim of the interview about the sexual life and instructing the patient how to understand each item, the patient is invited to specify the type of problem (libido, initiation, orgasm, ejaculation/erection for man, sexual intercourse frequency/desire) and to rate the degree of impairment (severity) from 1-3 points (mild-moderate-severe). During the first visit the patient is asked: "Do you have at present any problems with..." In the subsequent visits the rating should consider the period since the last visit.

Ten Key Questions to Explore the history of Sexual Dysfunction

1. How do you feel about your sexual life? Do you have any problems? If yes, could you please describe them
2. On the whole, do you experience pleasure or pleasurable feelings about sexual activity? (If not, we would like to explore the reason)
3. Do you feel that your overall desire (need) for the intimacy of sexual contacts has changed ? How severe is this change?
4. Do you feel that you have difficulties in getting sensually- or physically (erection, vaginal lubrication) aroused? If, yes could you rate the extent of the difficulty ?
5. Do you have any problem in reaching the climax (orgasm)? If yes, how severe is it ?
6. Have you noticed any changes in your satisfaction with orgasm? If yes, please describe
7. (for men specifically) Have you noticed any problem with erection/ejaculation? If yes, please describe
8. Are your sexual problems lasting or they emerge in particular situations only?
9. Do you have spontaneous sexual fantasies and thoughts?
10. On the whole, how satisfied are you with your sexual life?