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Original Study **OS2(1-7)**

Multidimensional assessment of quality of life and locus of control in elderly patients with type 2 diabetes: role of gender.

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Abstract

Type 2 Diabetes (T2D) in elderly patients is challenging and it may have a strong impact on patients' quality of life. In this study we evaluated whether personal, clinical, or gender-related variables may influenceDiabetes Specific Quality of Life(DSQoL) and locus of control (LOC) scores in a group of 100 elderly T2D outpatients (60% men, 40% women; mean age 72 years) on oral hypoglycaemic drugs and in good metabolic control (mean HbA1c 6.7%). Overall, women showed a greater cognitive impairment and a lower autonomy in daily lifeas compared to men. Mean DSQoL scores indicated a good quality of life, with a lower level of satisfaction in women (P=0.009).As for LOC, there was a high prevalence of the internal domain, indicating that these subjects had a good awareness of their own role in diabetes's management. Women reached lower scores in the LOC external domain, suggesting that external factors were perceived as less important determinants of diabetes' control in elderly women as compared to men (P=0.048). After stratifying all study variables according to QoL and LOC domains, only diabetes duration and hypoglycemic episodes were significantly associated with QoL, whereas only gender and the number of outpatient visits during the previous two years were associated with LOC domains. In conclusion, in elderly T2D patients QoL and LOC scores are clearly influenced by a number of clinical factors, including gender.

Key Words:multidimensional assessment, type 2 diabetes, gender, elderly

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Introduction

Type 2 diabetes (T2D) is a growing clinical and social burden worldwide, especially in the elderly population (1). Medical, psychological and social issues associated with ageing call for an individualized approach to T2D management in elderly patients, including a comprehensive geriatric assessment (CGA), as suggested by national and international guidelines (2-4). CGA includes a set of clinical tests exploring neurocognitive status, ability in basic and advanced activities of daily living (functional status), psycho-social issues and co-morbidities (5).Furthermore, diabetes have a strong impact on the quality of life, as assessed by a well-defined questionnaire (DSQoL), but this impact may differ according to gender and age (6,7).Demographic variables may also influence *Locus of control* (LOC), a validated tool to explorewhether patient perceives the responsibility of T2D management as depending either on himself (internal LOC) or on health professionals and/or relatives (external LOC),or on chance

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(Chance LOC) (8,9). DSQoL and LOC scores may have an impact on glucose control, but their role in clinical practice in elderly diabetic population has not been yet explored.Accordingly, the aim of our study was to evaluate whether personal, clinical, or gender-related variables may influence DSQoL and LOC scores in a group of elderly subjects with T2D.

Patients and Methods

One hundred T2DM elderly subjects treated withoral hypoglycaemic drugs (OHA), consecutively attending the Outpatient Clinic for Metabolic Disorders of the Department of Clinical and Experimental Medicine at Messina's University, were enrolled for the study.

Exclusion criteria for all participants were: current therapy with injective antidiabetic drugs (insulin or other), neoplastic, psychiatric or neurological diseases, severe sensory deficits, end-stage chronic renal failure. Subjects with a severe cognitive impairment, as defined by a Mini Mental State Examination (MMSE) score < 18 (10), were also excluded from the study.

Sociodemographic, clinical and lifestyle data were collected, including information on the complexity of diabetes management (number of OHA taken every day, number of outpatient visits and therapy changes in the previous two years) and the frequency of hypoglycaemic episodes in the previous six months. Anthropometric data, blood pressure and the following laboratory parameters were also measured: fasting blood glucose (FBG), HbA1c, lipid profile, creatinine, microalbuminuria.In order to perform a multidimensional evaluation of the study subjects, the following questionnaires were submitted to all participants: Mini Mental State Examination (MMSE) (10);Activity of Daily Living (ADL) scale(11);Instrumental Activities of Daily Living (IADL) scale (12);Diabetes Specific Quality of Life questionnaire (DSQoL)(7); and Locus Of Control (LOC) questionnaire(9).

Statistical analyses were performed using SPSS Statistics for Windows, version 15.0. Quantitative variables were expressed as means and qualitative variables as absolute value and percentage. The Student's t-test, the Pearson's chi-square and the Mantel-Haenszel were used for the comparisons. Values were considered to be statistically significant when $P<0.05$. Informed consent for the study was requested and obtained from all participants.

Results

Clinical characteristics of the subjects participating to the study are shown in Table 1. Overall, subjects were overweight and in good diabetes control in spite of a long disease duration, without any gender-specific difference. Lipid profile and renal function were acceptable in this population; women showed higher levels of HDL-cholesterol ($P=0.04$) and lower levels of creatinine ($P<0.001$), as compared to men.

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No significant gender differences were noted in systolic and diastolic blood pressure, FBG and microalbuminuria.

Only 7% of subjects referred one or more hypoglycemic episodes during the previous months, although 45% of them was treated with ≥2 OHAs, without any gender-difference. Also, no gender-differences were noted in the intensity of diabetes treatment as indicated by the number of daily OHAs taken, the frequency of outpatient visits (> 3 visits/year for 86% of the study participants) and the changes in oral therapy during the previous year.

Table 1. Clinical characteristics of T2D elderly subjects participating to the study, according to gender

	Total population	Men	Women	P
n	**100**	**60 (60%)**	**40 (40%)**	
Age (years)	**71.88 ± 6.95**	**72.51 ± 7.43**	**71.0 ± 6.17**	**-**
Level of school education (years)	**9.27 ± 3.75**	**9.41 ± 3.72**	**9.07 ± 3.83**	**-**
Diabetes duration (years)	**12.50 ± 9.74**	**12.05 ± 8.77**	**13.14 ± 11.06**	**-**
Weight (Kg)	**73.73 ± 13.43**	**77.4 ±12.49**	**68.62 ± 13.16**	**<0.001**
BMI (Kg/m^2)	**27.75 ± 5.20**	**27.69 ± 5.25**	**27.83 ± 5.19**	**-**
Waist circumference (cm)	**100.80 ± 11.39**	**103.04 ± 11.76**	**98.56 ± 10.78**	**-**
Systolic Blood Pressure (mmHg)	**138.19 ± 14.68**	**139.34 ± 15.40**	**136.91 ± 13.86**	**-**
Diastolic Blood Pressure (mmHg)	**84.01 ± 8.00**	**84.51 ± 9.30**	**83.45 ± 6.30**	**-**
Fasting Blood Glucose (mg/dl)	**170.03 ± 45.03**	**176.13 ± 43.26**	**163.10 ± 46.35**	**-**
HbA1c (%)	**6.71 ± 0.66**	**6.73 ± 0.66**	**6.70 ± 0.66**	**-**
Patients with HbA1c ≤7.5% n (%)	**94 (94)**	**55 (92)**	**39 (97.5)**	**-**
Total cholesterol (mg/dl)	**163.49 ± 29.20**	**159.49 ± 28.05**	**169.40 ± 30.20**	**-**
HDL-cholesterol (mg/dl)	**49.32 ± 12.85**	**47.10 ± 11.38**	**52.51 ± 14.25**	**0.04**
LDL-cholesterol (mg/dl)	**88.30 ± 25.89**	**87.54 ± 26.13**	**89.47 ± 25.82**	**-**
Triglycerides (mg/dl)	**130.02 ± 60.45**	**129.83 ± 59.24**	**130.29 ± 62.93**	**-**
Creatinine (mg/dl)	**0.98 ± 0.25**	**1.08 ± 0.25**	**0.85 ± 0.18**	**<0.001**
eGFR C-G (ml/min)	**70.43 ± 23.04**	**70.98 ± 22.95**	**69.77 ± 23.40**	**-**
Microalbuminuria n (%)	**21 (15.5)**	**13 (9.62)**	**8 (5.92)**	**-**
Episodes of hypoglycemia n (%) *	**7 (7)**	**3 (5)**	**4 (10)**	**-**
Patients on 2 or more OHA	**45 (45)**	**28 (47)**	**17 (42.5)**	**-**
Patients with 2 or more changes n (%) (%) ****	**8 (8)**	**3 (5)**	**5 (12.5)**	**-**
Patients with 3 or more visits n (%) ***	**86 (86)**	**51 (85)**	**35 (87.5)**	**-**

Data are mean ± SD; n, %.OHA oral hypoglycaemic drugs
* Patients with at least one episode of hypoglycemia in the six months preceding the study
** Changes of hypoglycaemic therapy in the two years preceding the study
***Outpatient diabetic visits carried out in the two years preceding the study

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Table 2 shows the results of the tests performed for the multidimensional assessment. Women showed lower MMSE scores as compared to men (P=0.046), indicating a worse neurocognitive status and a mild cognitive impairment (MMSE score < 24) was observed in 29 subjects (15 women and 14 men). Women also showed lower ADL scores, with more women showing ADL scores<6 than men (14% vs 6%, P=0.004), indicating a lower self-sufficiency in basic activity of day –life. The same difference was noted concerning independence in instrumental activity of day –life (IADL score <8 in 18% of men and in 36% of women, P=0.032).

Mean DSQoL scores indicated an overall good quality of life in both gender, but with an higher DSQoL-satisfaction score in women as compared to men (P=0.009).As for LOC, there was an high prevalence of the internal domain in the study participants, indicating a good awareness of their own role in diabetes's management. Only gender and the number of outpatient appointments during the previous two years were associated with LOC domains. Women reached lower scores in the LOC-external domain as compared to men (P=0.048), suggesting that they less perceived the impact of external factors.

Subjects undergoing to a greater number of controls during the previous two years showed higher scores in the external LOC domain (25.30 ± 5.74 in subjects with ≥ 3 visits/2 years *vs.* 21.44 ± 4.64 in subjects with 1-2 visits/2 years; P<0.001).

Table 2: Multidimensional assessment in T2D elderly subjects participating to the study, according to gender

	Total population	**Men**	**Women**	**P**
MMSE score	25.61 ± 2.91	26.06 ± 2.79	24.98 ± 2.99	0.046
MMSE <24 n (%)	29 (29)	14 (23)	15 (37)	-
ADL score	5.80 ± 0.61	5.95 ± 0.43	5.58 ± 0.76	0.002
ADL <6 n (%)	20 (19.2)	6 (9.83)	14 (32.55)	0.004
IADL score	7.66 ± 0.91	7.75 ± 0.57	7.53 ±71.24	-
IADL score <8 n (%)	26 (26)	11 (18)	15 (36)	0.032
DSQoL: *Satisfaction*	32.41 ± 9.35	30.41 ± 8.74	35.26 ± 9.55	0.009
Impact	37.18 ± 8.64	37.08 ± 8.66	37.33 ± 8.71	-
Worry	8.32 ± 2.89	8.10 ± 3.01	8.63 ± 2.72	-
LOC: *Internal*	29.53 ± 6.34	29.49 ± 6.06	29.58 ±6.78	-
External	24.63 ± 5.73	25.51 ± 5.38	23.40 ± 6.05	0.048
Chance	18.25 ± 7.71	18.26 ± 7.47	18.23 ± 8.13	-

Data are mean ± SD; n, %.

MMSE:Mini Mental State Examination; ADL: Activities of Daily Living

IADL: Instrumental Activities of Daily Living

DSQoL: Diabetes Specific Quality of Life

LOC: Locus of Control

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Furthermore, as shownin **Table 3**, after stratifying all study variables according to QoL and LOC scores, only diabetes duration and the number of hypoglycaemic episodes were significantly associated with QoL.

Table 3: DSQoL *(Diabetes Specific Quality of Life)*scores in subjects participating to the study, according to clinical characteristics

	Satisfaction	**Impact**	**Worry**
Total population	32.41 ± 9.35	37.18 ± 8.64	8.32 ± 2.89
Duration of diabetes			
≤ 10 years	31.2 ± 9.62	35.48 ± 9.06	8.24 ± 2.74
> 10 years	33.62 ± 9.14	38.94 ± 8.08	8.46 ± 3.07
P	-	0.04	-
*Episodes of hypoglycaemia**			
Yes	42.43 ± 10.41	48.57 ± 14.84	10.43 ± 3.69
No	31.69 ± 8.90	36.36 ± 7.49	8.16 ± 2.79
P	0.003	<0.001	0.04

Data are mean ± SD.
* One or more episodes of hypoglycemia in the six months preceding the study

Discussion

Management of T2D involves heavy intervention on lifestyle, complex therapy programs and recurrent outpatient evaluations. Patients' ability to follow the suggested treatment, i.e. adherence, can be deeply influenced by psycho-social and cognitive wellness, especially in older subjects.Although QoL and LOC are two important features of diabetes care plan, factors influencing these parameters in clinical practice are not known. Our data show an overall good DSQoL in this study population, with diabetes duration and hypoglycaemic episodes having the greater impact on QoL. As for LOC, our study subjects showed good awareness of their own role in diabetes's management, as suggested by the prevalence of internal domain over the others. Conversely, other clinical factors do not seem to influence QoL or LOC scores. These results suggest that elderly patients attending a third-level facility of diabetes care are adequately empowered to manage their disease and that they are overall satisfied with the plan of care, so that T2D does not seem to negatively influence their QoL or LOC. Our analysis shows significant gender-differences in several tests, with elderly T2D women showing a greater cognitive impairment and a lower autonomy in daily life; furthermore, T2D women had a worst QoL and perceived less help from others (lower external-LOC scores).

These results are in line with several evidences showing that women have a higher rate of depression, cognitive impairment and loss of autonomythan men (13-15). The complex link among ageing,

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psychological attitude and mental status may explain how depression and cognitive decline may lead to a progressive functional disability. These gender differences may be ascribed to hormonal, metabolic and psyco-social factors (13-15).

Some limitations, such as the relatively small number of included subjects and the cross-sectional design of the study, should be taken into account; furthermore, almost all our study subjects were in good glycaemic control, in spite of the older age and the T2D duration; consequently the impossibility to perform a comparison between subjects in good and subjects in bad metabolic control should be acknowledged among the limitations of the study.

In conclusion, our study shows that in elderly patients with T2DM attending an outpatient diabetes center quality of life and locus of control, assessed by standardized questionnaires, are influenced by a number of clinical factors, including gender.

Supplemental Table –Test performed in the study

Test	*What is evaluating*	*Scores/Domains*	*Interpretation of the scores*
Mini Mental State Examination (MMSE) (10)	The Mini Mental State Examination (MMSE), is a fast cognitive screening test. It consists of 11 questions that assess 5 cognitive functions	Investigated areas are: Orientation , registration , attention and calculation , recall and language. The maximum score is 30.	A score between 30 and 24 indicates the absence of cognitive impairment, a score of 23 to 18 is an index of mild cognitive impairment, a score of 17 and 0 indicates a severe cognitive impairment .
the Activity of daily Living (ADL) scale (*11*)	The Activities of Daily Living, ADL is the most used instrument for geriatric patient evaluation. ADL scale value 6 basic activities of daily living.	These activities are: Having a bath, dress, moving, autonomy in going to the toilet, urinary and fecal continence, and feeding.	The maximum score is 6 (full autonomy) and the lowest score is 0 (minimal autonomy).
Instrumental Activities of Daily Living (IADL) scale (*12)*	Instrumental Activities of Daily Living scale, IADL, is an instrumental activities evaluation scale, evaluating the performances in complex but necessary activities in older people	These activities are: using the telephone, make a shop, make food, cleaning house, washing clothes, use of transport, take drugs, manage money. IADL scale have only two answer: 1 (able to make activity) 0 (unable to make activity).	The global score is the sum of the activities of which the patient is able. The maximum score is 8 (full Instrumental Activities autonomy) and the lowest score is 0 (minimal Instrumental Activities autonomy). There is not a disability threshold score.
Diabetes Specific Quality of Life questionnaire (DSQoL)(*7*)	The DSQoL questionnaire includes three domains, respectively indicating satisfaction with the management of the disease, impact of diabetes on patient life and worry about diabetes.	DSQoL domains are: Satisfaction (14 questions, domain score from 14 to 70); Impact (28 questions, domain score from 28 to 92); Worry (5 questions, domain score 5 to 25).	Lowering the scores of any of the DSQoL domains indicates a shift toward a better quality of life
Diabetes-specific Locus Of Control (LOC) questionnaire (9)	Assess patients' perception on who is in charge of the control over diabetes. It consists of 18 questions in three different domains, each with a score from 6 to 36.	LOC Domains are: Internal (the LOC lies within the patient); External or Powerful Others (either health professionals or nonmedical powerful individuals control patient's diabetes); and Chance (patient's diabetes is controlled by chance or fortune).	The domain with the highest score indicates the LOC of diabetes-related events, as perceived by the patient.

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