Treating depression: what patients want. Findings from a randomized controlled trial in primary care

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Treating Depression: what patients want, findings from a Randomized Controlled Trial in primary care

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Abstract

*Objective***:** To highlight clinical and socio-demographic factors associated with patients' preference in the treatment of depression, we conducted a Randomized Controlled Trial (RCT) comparing the efficacy of Selective Serotonin Reuptake Inhibitors (SSRIs) and Interpersonal Counseling (IPC) in patients with a major depressive episode. *Methods*: Patients, recruited from a psychiatric consultation service in the primary care setting, were asked to express their preference for the type of treatment before randomization to one of the two intervention arms. Severity of depressive symptoms and functional impairment were assessed using the 21-item Hamilton Rating Scale for Depression (HDRS) and the Work and Social Adjustment Scale (WSAS), respectively. *Results*: 170 patients were evaluated, 87 (51.2%) patients expressed their preference for IPC and 83 (48.8%) for SSRIs. Depression severity and treatment preference showed significant correlations. Preference for IPC was related to mild depression and greater functional impairment, while patients with moderate or severe depression were more likely to prefer medication. Remission rates and functional level were not related to treatment preference at the end of the study. *Conclusion*: Treatment preference is a critical factor, influenced by clinical and socio-demographic characteristics and further studies are needed to improve its clinical relevance.

Keywords: depression, primary care, psychotherapy, antidepressant, interpersonal counseling, preference

Introduction

Major Depression is among the most common psychiatric conditions, representing a public health issue that leads to poor quality of life and increases disability and personal suffering [1]. Despite the availability of evidence-based treatments, the full remission of symptoms is not achieved in a high proportion of patients ranging from 30 to 50% [2]. Adherence to antidepressant drugs remains low, especially in the primary health care setting [3]. Recent evidences also showed that the benefit of antidepressant medication compared with placebo increases with severity of depressive symptoms [4], while for mild to moderate depression the efficacy of a brief structured psychosocial intervention could be higher than that of SSRIs [5].

By addressing the growing need to optimize the available resources in the primary care setting where psychological interventions are often lacking, the research has recently focused on tailored interventions. In particular, one of the factors more studied is the patients' treatment preference as differential predictor of depression outcome [6, 7]. It is increasingly undeniable that patients' propensity for treatment options may vary and that a patient-centered approach is essential for an effective management [8-10].
Previous studies on patients' preference showed how it may affect clinical and relational aspects of the caring process, including the beginning of the prescribed treatment, compliance to it and the degree of the therapeutic alliance with the clinician [11]. On the other hand, there is contrasting evidence that the choice of pharmacological or psychological interventions based on the preference may provide advantages in terms of remission of the initial depressive symptoms [12].

While it is well-established that depressed patients more frequently favor psychological interventions [8], there are few data on factors associated with treatment preference [13]. Female gender, high level of education and a family history of depression have been related with a propensity for psychotherapy [14]. Likewise, it has been highlighted how preference may vary according to age, race, working status, history of previous treatments and patients' opinions about the causes and consequences of depression [14-18]. There are even fewer available indications concerning the relation between clinical variables and treatment preference. Among these observations, the effect of depression severity has been mixed with some studies finding no difference in preferences [14, 15] and others reporting a positive relation between a more severe depressive symptomatology and the choice of pharmacological intervention [17, 19]. However, at least one study has provided the opposite evidence, showing that higher levels of depressive symptoms were associated with more negative attitude towards antidepressant treatment. [20].

Since the majority of studies on depression treatment preference has been conducted in English-speaking countries, there is a need to broaden the research on this issue in other contexts. It is possible to hypothesize important differences that may appear between countries, related to socio-cultural factors or to health care system's organization.

In order to evaluate socio-demographic and clinical factors associated with patients' treatment preference, we use data from a Randomized Controlled Trial (RCT) conducted in Italy and comparing a brief psychological intervention, the Interpersonal Counseling (IPC), with SSRIs in a sample of depressed primary care patients. In addition, our trial allow to assess the impact of preference on outcome and thus to expand current knowledge on this controversial topic.

Methods

Design

This is a multi-center RCT comparing IPC versus SSRI for primary care patients with major depression (DE-PICS Study). The full protocol for the DEPICS study has been described in detail in a previous work [7]. Be-

fore randomization to one of the two interventions, patients were asked to express their preference for the psychological or for the pharmacological treatment.

The protocol of this study was approved by the Ethical Committee of University Hospital of Bologna and registered in the Australian New Zealand Clinical Trials Registry (ANZCTR) as ACTRN 12608000479303.

Participants

Patients were recruited from university-based psychiatric consultation-liaison services specifically dedicated to Primary Care Physicians (PCPs) that were encouraged to refer patients recognized as suffering from depression; patients were seen by a consultant psychiatrist and evaluated for the possible inclusion in the study.

Inclusion criteria were: age of 18 years or more, a diagnosis of major depressive episode, a Hamilton Depression Rating Scale (HDRS, 21 item version) score equal or greater than 13 [21], and no more than one past Major Depressive Episode (MDE) treated with antidepressants or psychotherapy. We excluded patients with two or more previous depressive episodes treated with antidepressants or psychotherapy and with Borderline or Antisocial Personality Disorder because of the different pattern of response to treatment and the less favorable prognosis [22, 23].

Interventions

IPC is a brief manualized treatment derived from Interpersonal Psychotherapy and suitable for different conditions such as Subthreshold depression and Major depression [24, 25]. IPC consisted of a maximum of six thirty-minute sessions, with the initial session being longer (1 hour), and was self-dosing: the patient could choose in advance how many sessions to attend and many patients were satisfied with fewer than six sessions [26].

The pharmacological treatment consisted of sertraline or citalopram, chosen to their generally low interaction rate, low cost and wide diffusion among PCPs. Citalopram was started at 10-20 mg and increased up to 60 mg if needed, sertraline was started at 25-50 mg and could be increased up to 200 mg.

Measures and outcomes

Diagnosis of MDE was made with the Mini International Neuropsychiatry Interview (MINI) Plus [27] while the severity of symptoms was assessed using the 21-item Hamilton Rating Scale for Depression (HDRS) [21], which is the most widely used depression assessment scale. To define baseline depression severity, we use the cut-offs based on Zimmerman et al. [28]: a score lower than 7 indicates absence of depression, from 8 to 16 mild depression, from 17 to 23 moderate depression and higher than 24 severe depression.

The primary outcome measure was remission of depressive symptoms at 2 months, defined as a HDRS score of 7 or less. Secondary outcome measure was functional impairment that was measured with the Work and Social Adjustment Scale (WSAS), a 5-item self-report scales investigating ability to work, home management, social leisure, private leisure, and relationships [29].

Assessments were conducted by research personnel not involved in patients treatment and trained to the use of instruments and scales. Raters who administered assessment's instruments were different from the clinicians who provided psychiatric consultation to PCPs and delivered pharmacological or psychological interventions. Efforts were made to keep raters blind to randomization assignment.

Analysis

For the purposes of this study, we analyzed data from 5 of 9 participating centers due to missing information about preference. In particular, the included sites were: Bologna (coordinating center), Cagliari, Foggia, Pavia, and Torino. In addition, we excluded those patients received a combined treatment after the 2-months follow-up.

Chi-square test (χ2) an T-test were used to compare the frequency of categorical variables between groups and the means of continuous variables between two or more groups, respectively. Factors that showed significant correlation with patients' preference were further evaluated using multiple regression analysis and controlling for age and gender.

To evaluate the impact of preference on outcome, we divided our sample in four groups obtained by crossing treatment arm and preference. Proportion of remission and HDRS mean score were calculated in the four groups at 2 and 6 months follow ups and compared with Chi-square test (χ^2) a T-test, respectively. Bonferroni correction for multiple comparison was applied to the significant level. Data were analyzed by using SPSS for Windows, version 22.0.

Results

Data on 170 patients, who indicated their treatment preference and completed the study protocol, were examined. Out of these, 87 (51.2%) patients expressed their preferences for IPC and 83 (48.8%) for SSRIs. Socio-demographic and clinical factors associated with treatment preference are shown in Table 1.

With regards to depression severity, the group preferring the psychological intervention had a higher proportion of mild depression (p=0.002) and a lower HDRS mean score (p=0.017) compared to those who preferred the drug treatment. In addition, participants with a propensity for psychological intervention were more likely to report poor perceived functioning measured with the WSAS than patients preferring medications (p=0.034). Analyzing the scores of the instrument WSAS, those preferring the psychological intervention perceived a greater level of impairment in all the five items in the list. The score difference was statistically significant for 2 items, those regarding private leisure activities (p=0.009) and social leisure activities (p=0.042). Considering socio-demographic characteristics, a higher proportion of employed was in the group preferring the psychological intervention (p= 0.013).

The treatment arms were balanced in the two preference groups: 50.0% in the group preferring psychological intervention and 44.6% in the group preferring medication received IPC (p=0.289). After randomization, 44 (25.9%) patients who had expressed their preference for IPC received this intervention, while 46 (27.1%) patients who had expressed their preference for SSRIs received the medication.

Regarding the impact of preference on outcomes at 2 and at 6 months, our findings did not suggest an advantage for patients receiving the preferred intervention. The proportion of remitters and the HDRS mean score were similar in the groups obtained by crossing treatment arm and preference, with the exception of remission at 2-months follow-up (Table 3). Considering the subsample preferring SSRI, we found a higher remission rate in patients randomized to IPC than those allocated to medication arm (p=0.001).

Discussion

The main objective of this study was to analyze factors associated with depression treatment preference among patients participating in a RCT that compared pharmacological and psychological interventions. Additionally, we evaluated the effect on outcome of matching or mismatching patients to the preferred intervention.

Firstly, we found that patients with mild depression were more likely to prefer IPC, while patients with moderate-severe depression were more likely to prefer medications. Compared to previous results [13], this finding may increase our understanding on the relationship between depression severity and treatment preference.

With regard to the primary care setting, our data are in line with those of Chilvers et al. [19], in which depression severity was assessed only by PCP's clinical rating and with those of Gum et al. [30] in a sample

of older adults suffering from Major Depression, Dysthymia or both. Differently, our observations are in contrast with Houle et al. [14] in a sample of patients at the first depressive episode. However, our study was more focused on a specific diagnosis, as it included only patients with a MDE, and more representative with patients of all age groups and cases of recurrent depression (patients at their second depressive episode).

Furthermore, to our knowledge, this is the first study to show a clear distinction between patients' preferences based on symptoms severity, as defined by the HDRs scores, which is the most widely used depression assessment scale by current meta- and mega-analyses examining the treatment significance of depression [28]. Nevertheless, our results are also consistent with the NICE guidance recommendations of promoting a patient centered approach and treating mild depression with psychosocial interventions [10].

Interestingly, the relationship between treatment preference and severity of the baseline depressive symptoms and perceived functional impairment varies. In particular, participants with moderate-severe depression were more favorable to medications, while those with higher WSAS scores preferred the psychological intervention. Considering the broad range of symptoms investigated by these scales, we suppose that patients with higher scores in the HDRS suffered especially from physical symptoms as sleep disorders, anxiety somatic signs or pain and therefore were more prone to drug treatment. Similarly, we could assume that patients reporting higher levels of social impairment chose a psychological intervention. This seems confirmed by the WSAS single items analysis as these patients were more likely to perceive a greater impairment of their private and social leisure activities. Albeit indirectly, this finding seems to be consistent with previous evidences indicating that patients who believe that their depressive symptoms are due to biological reasons choose more frequently the pharmacological treatment, while patients who primarily associated their depression with psychosocial causes, like stressful life events or interpersonal problems, take greater account of psychological interventions [18, 14].

Regarding socio-demographic characteristics, preferences did not change significantly in relation to factors found in previous studies such as gender [14, 31], age [15] or level of education [14]. Interestingly, as previously shown by Dobscha et al, being employed was related to a preference for psychotherapy [17]. In this regarding, we assumed that workers' preference for our psychological intervention was also due to the IPC specific characteristics, as they may have supposed to have the chance to discuss their working problems during the treatment [32]. However, after the multiple comparison, patients' working status was no longer significantly associated with treatment preference.

Finally, regarding the impact of patients' preference on treatment outcomes, there were no significant advantages on depressive symptoms and on functioning for those patients matched to their preference and those who were not. The statistically significant difference in the 2-months remission rate of patients preferring SSRIs and randomized to IPC was not confirmed by the difference in the HDRS' average scores and was no longer significant at 6 months follow-up. This finding could be the result of a bias due to the splitting of the sample, resulting in small groups with low statistical power. The lack of influence of preference on treatment efficacy is consistent with most of the data considered in the Gelhorn et al. review [12], who concluded that available studies have provided only mixed results concerning the effect of preference on outcomes. A possible explanation, which should be addressed by future research, may lie in the lack of a psychoeducational intervention focusing on treatments before the preference assessments phase, as such approach could significantly modify patients' attitude toward treatments.

Examining our results, we have to consider some limitations. Firstly, our analysis were exploratory and not primary measures in the DEPICS study, therefore a multiple comparisons not guided by a priori hypotheses may be associated with the risk of spurious findings. In the second place, we did not assess participants' opinions and beliefs on depression, which have been found to be linked to treatment preference, as mentioned above [14, 18, 33]. In addition, we did not record the history of previous treatments, which could have had significant implication on patients' choice. Finally, another important limitation was that participants were specifically selected for a RCT and consequently not fully representative of patients seen in clinical practice. In particular, our sample possibly had a low level of impairment, as it was mainly composed by patients with mild or moderate depression with no more than one previous depressive episode.

This study also provides some indications for the clinicians in the management of depressive patients' preference. For example, when discussing with a patient who prefers psychotherapy rather than drugs, the

clinician should examine more deeply if such preference is related to a significant impairment of the social functioning. Moreover, if the preferred intervention is not available, clinicians could reassure and inform patients that treatments generally show similar efficacy, regardless of their preference.

Conclusions

Our study suggests that mild depressive symptoms and high levels of perceived functional impairment are associated with the preference for the psychological treatment. Moderate to severe depressive symptoms are instead related to the preference for the psychopharmacological intervention.

Patients' preference in the treatment of Depression appears as a complex construct, which is modulated by socio-environmental and clinical factors and, consequently, better understood from a biopsychosocial perspective. Further research should evaluate not only the impact of preference on interventions' efficacy, but also how this factor could be better considered by the clinician during the shared decision making process of the treatment. A psychoeducational intervention on preference as a potentially modifiable variable could be extremely useful in the physician-patient relationship and for the Depression management.

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Table 1. Socio-demographic and clinical factors associated with treatment preference

	Total	IPC	SSRIs	P
	n=170	n= 87	n=83	
Gender: F, n (%)	126 (74.1)	70 (79.5)	57 (68.7)	.073
Age, mean (SD)	46.18 ±14.66	44.37 ±14.68	48.09 ±14.48	.101
Female, <45 years, n (%)	54 (43.2)	34 (49.3)	20 (35.1)	.077
Living with others, n (%)	142 (84.0)	76 (88.4)	66 (79.5)	.087
Compulsory Education, n (%)	76 (47.7)	41 (42.7)	35 (20.8)	.311
Employed, n (%)	93 (55.0)	55 (64.0)	38 (45.8)	**.013**
Previous MDE, n (%)	132 (77.6)	72 (82.8)	60 (72.3)	.073
HDRS baseline <17, n (%)	104 (61.2)	62 (71.3)	42 (50.6)	**.002**
HDRS baseline, mean (SD)	17.21 ±3.44	16.59 ±3.5	17.86 ±3.25	**.017**
WSAS baseline, mean (SD)	18.95 ±8.56	20.30 ±8.33	17.51 ±8.62	**.034**
WSAS impairment in ability to work, mean (SD)	3.96 ±2.32	4.18 ±2.24	3.72 ±2.39	.194
WSAS impairment in home management, mean (SD)	3.53 ±2.20	3.67 ±2.12	3.39 ±2.29	.417
WSAS impairment in Private leisure activities, mean (SD)	4.20 ±2.32	4.64 ±2.31	3.72 ±2.25	**.009**
WSAS impairment in Social leisure activities, mean (SD)	4.24 ±2.37	4.60 ±2.44	3.85 ±2.26	**.042**
WSAS impairment in close relationships, mean (SD)	3.02 ±2.27	3.21 ±2.34)	2.83 ±2.19	.283

Abbreviations: F: female; HDRS: Hamilton Depression Rating Scale; IPC: interpersonal Counseling; MDE: Major Depressive Episode; n: number; SD: standard deviation; SSRIs: Selective Serotonin Reuptake Inhibitors; WSAS: Work and Social Adjustment Scale

Table 2. Multiple regression analysis evaluating the impact of occupation, depression baseline severity and functioning on treatment preference*

	T	SE	Beta	t	P
Occupational status, Employed	-.091	.078	-0.91	-1.168	.245
Mild Depression at the baseline (HDRS < 17)	.245	.076	.245	3.217	.002
WSAS baseline score	-.011	.005	-.184	-2.398	.018
R^2=.126					

Abbreviations: HDRS: Hamilton Depression Rating Scale; WSAS: Work and Social Adjustment Scale

* The model was corrected by age and gender

Table 3. Treatment outcomes in patients divided by preference and randomization arm

	Preference	*IPC*	*SSRI*	*SSRI*	*IPC*
	Randomization	*IPC*	*SSRI*	*IPC*	*SSRI*
		n=44	n=46	n=37	n=43
Baseline	HDRS, mean ±sd	16.39 ±3.64	18.13 ±3.38	17.59 ±3.18	16.77 ±3.42
2-Months	HDRS, mean ±sd	9.00 ±4.93	9.88 ±5.57	7.21 ±3.88	9.20 ±5.37
	Remission, n (%)	20 (45.5)	15 (32.6)*	26 (70.3)*	21 (48.8)
6-Months	HDRS, mean ±sd	5.92 ±4.92	5.74 ±2.60	6.32 ±3.48	5.89 ±3.70
	Remission, n (%)	26 (59.1)	30 (65.2)	22 (59.5)	28 (65.1)

Abbreviations: HDRS: Hamilton Depression Rating Scale; IPC: interpersonal Counseling; n: number; SD: standard deviation; SSRIs: Selective Serotonin Reuptake Inhibitors; WSAS: Work and Social Adjustment Scale

*The difference in the remission rate between patients preferring SSRI randomized to SSRI and those preferring SSRI randomized to IPC was statistically significant (p=0.001). We applied Bonferroni correction to all the analysis; for n=6 comparisons the new significance level was set to 0.05/6=0.0083.