LONG-ACTING INJECTABLE ARIPIPRAZOLE: REAL WORLD EFECTIVENESS. A 6-MONTH FOLLOW UP.

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RATIONALE

Schizophrenia is a chronic disease with periods of remission and relapse. Antipsychotic drugs represent the mainstay of treatment for this disease. Long-acting injectable aripiprazole (AOM) is the last active principle available in our country and its evidence of use in real clinical practice is still limited. Long-acting injectable antipsychotic therapies may offer benefits over oral antipsychotics in patients with schizophrenia, specially, in terms of compliance to treatment. However, there is still a lack of real-world studies assessing the effectiveness of these therapies. Moreover, long-term antipsychotic treatments have been linked to a wide range of side effects (weight gain, hyperprolactinemia and dyslipidemia among others). Likely, differences between antipsychotics may impact on these clinical outcomes.

OBJECTIVE: This study aimed to explore the safety, tolerability, and treatment response of aripiprazole monohydrate (AOM) once monthly in non-acute but symptomatic adult patients switched from previous therapy with frequently used oral or injectable atypical antipsychotics.

METHODS

In our sample, 56 patients were recruited from two outpatient clinics linked to Marqués de Valdecilla University Hospital. All of them, under diagnosis of Schizophrenia and in conditions of clinical stability. Clinical efficacy measures (BPRS, BPRS(+), BPRS (-), CGI), all-cause discontinuation rate and mean time to discontinuation (effectiveness), quality of life scale (QLS), and side-effect profile (UKU, BAS, SARS, SALSEX), were evaluated over a 6-month follow-up. Patients were switched to aripiprazole monohydrate once-monthly (AOM) from daily oral treatment or monthly injectable treatment with either aripiprazole (n = 27), olanzapine (n =7), paliperidone extended-release (PP1M) (n = 10), quetiapine (n = 4), or risperidone (n = 8). Baseline, 3-month and 6-month blood analyses were performed to assess metabolic and endocrinological parameters.

RESULTS (1): Efficacy, quality of life, safety.

85.2% of patients presented with a similar or improved clinical condition regarding the CGI scale (with a 59.3% of improvement rate). Likewise, there was a statistically significant improvement in EEAG, QLS, BPRS, BPRS (+) and BPRS(-). There was no statiscally significant increase in the rate of emergence of akathisia or other extrapyramidal symptoms. Though, no global statistically significance was found for the sex functionality, when exclusively patients with sexual dysfunction were analyzed, we found a slight statistically significant improvement (p=0.05).

ICG Baseline	Frequency (N)	Percentage (%)
Slightly ill	8	29,6
Moderately ill	9	33,3
Markedly ill	8	29,6
Severely ill	2	7,4
Total	27	100,0

ICG 6-Month	Frequency (N)	Percentage (%)
Much improved	4	14,8
Moderate improvement	4	14,8
Slight improvement	8	29,6
No change	7	25,9
Slight worsen	4	14,8
Total	27	100,0

	baseline		6-month		
Clinical Scales	mean	SD	mean	SD	(F; p)
BPRS	40.00	9.32	34.11	9.12	(F=20.82; p<0.001)
BPRS (+)	8.30	3.12	6.33	2.42	(F=26.27; p<0.001)
BPRS (-)	9.11	3.03	7.81	2.99	(F=14.51; p=0.001)
EEAG	57.33	16.98	68.96	18.46	(F=11.02; p=0.003)
SALSEX	4.9	5.27	4.10	4.15	(F=1.53; p=0.229)
QLS	61.82	28.04	71.23	25.35	(F=8.61; p=0.010)
BARNES	0.64	1.61	0.84	1.91	(F=0.34; p=0.564)
SIMPSON- A	0.00	0.00	0.56	2.29	(F=1.12; p=0.305)

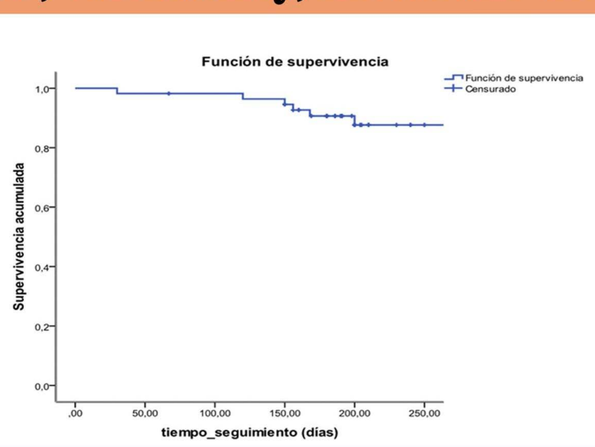
RESULTS (2): Effectiveness, tolerability, metabolic measures.

Global comparisons

	Chi-squared	gl	Sig.
Log Rank (Mantel-Cox)	1,512	2	,470

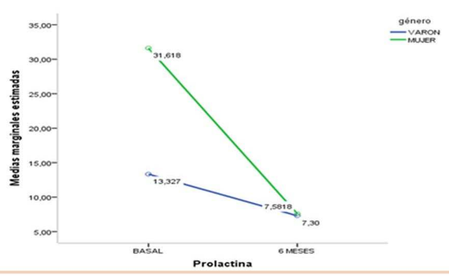
No statistically significant differences between the reasons for discontinuation were found.

Only 6 patients (89.3% survival) discontinued treatment. Overall, 10.7% of patients discontinued AOM treatment prior to 6-month endpoint.

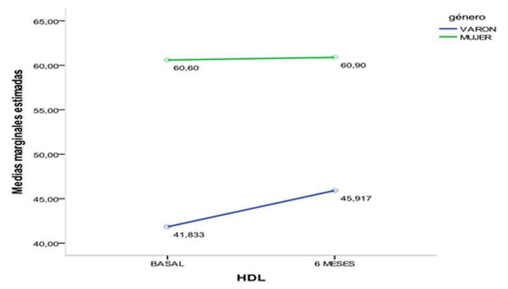


parameter	baseline		6-month	
	mean	SD	mean	SD
BMI	27.89	5.35	27.41	4.81
P. Abdominal	93.65	17.92	93.12	16.87
SBP	121	15.75	116	13.88
DBP	74.88	9.29	73.24	8.17
HR	76.81	14.03	76.62	12.01
Glu	94.85	16.96	96.81	21.50
TG	139.29	125.79	132.04	77.64
HDL	50.63	14.06	52.72	15.68
LDL	115.59	34.73	117.09	34.71
PRL	23.63	30.13	7.44	8.58

After repeated measures following a general linear model, no statistically significant differences were found for metabolic and endocrinological measures but for Prolactin (F=6.41; p=0.002) , which showed a significant decrease on the blood samples after 6-month of AOM treatment.



Interestingly, a differential gender analysis showed: a trend towards a more rapid and dramatic decrease in prolactin measures among women. On the other hand, there was a significant increase in HDL measures among men. May AOM represent a metabolic pro-factor in this sub-sample?



CONCLUSIONS:

These data illustrate that stable, non-acute but symptomatic patients either on oral antipsychotic therapy or under monthly antipsychotic treatment may show clinically meaningful improvement of psychotic symptoms, tolerability involving relevant side effects and quality of life perception. AOM may represent a differential pro-metabolic treatment with improvements in PRL and HDL in women and male populations respectively. It may also improve sexual function regarding other antipsychotic treatments. The findings are limited by the naturalistic study design; thus, further studies are required to confirm the current findings.