TAPENTADOL PR IN FRAGILE OVER EIGHTY YEARS OLD PATIENTS WITH NON-CANCER CHRONIC PAIN

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Introduction

Chronic pain is one of the most complex therapeutic challenges. Moreover, dealing with fragile elderly patients having comorbidity, generally due to multiple organ dysfunction, is actually braving. Any therapeutic approach must consist of drugs with strong efficacy and good tolerability[1]. Tapentadol, an analgesic drug with a dual mechanism of action, as an opioid agonist and noradrenaline reuptake blocker, could provide the key of an effective analgesic action with a good tolerability profile, even in elderly patients[2,3]. The availability of different doses-including the new 25 mg dose-may lead to a tailored treatment based on pain characteristics and patients' needs.

Objective

Aim of this study was to evaluate efficacy and tolerability of tapentadol PR using the new 25 mg dose in our clinical practice, considering a sample of fragile over eighty years old patients with non-cancer chronic pain.

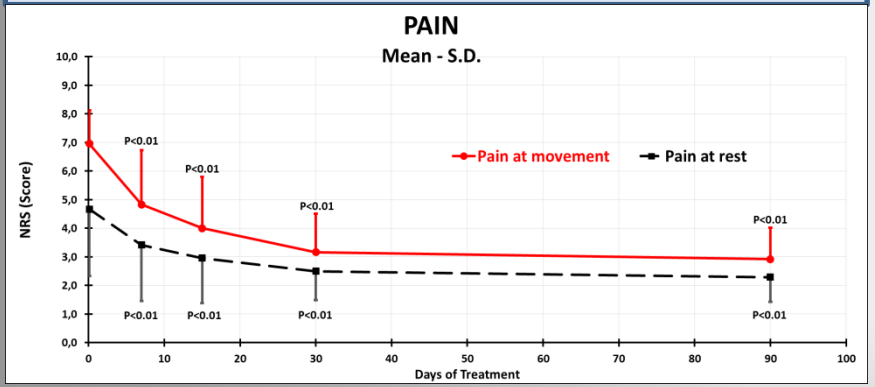


Fig. 1 – Pain intensity at rest and at movement in 30 old fragile patients treated with tapentadol.

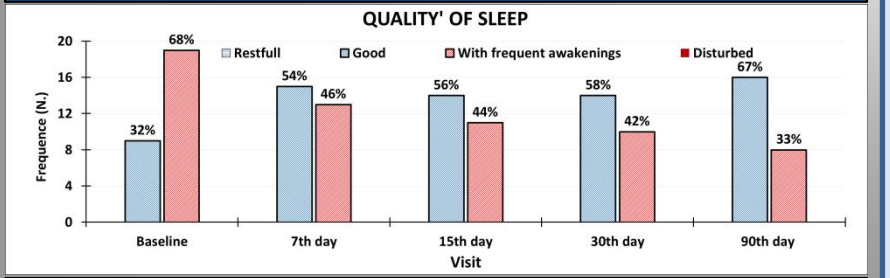
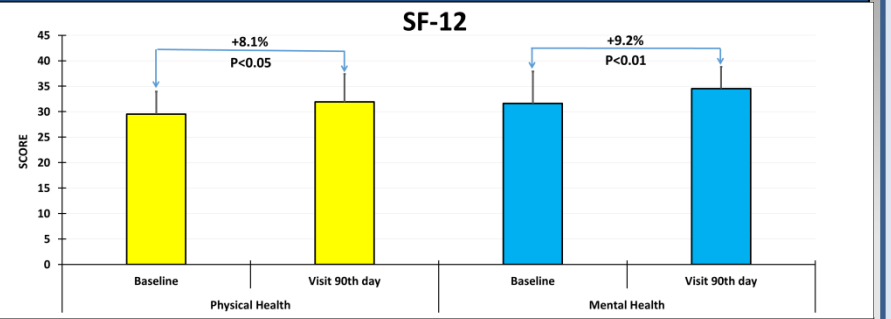


Fig. 2 – Quality of sleep using a 4-point verbal scale from 0 to 3 (0= disturbed; 1= with frequent awakenings; 2= good; 3= restful).

Fig. 3 –SF-12 physical and mental health from baseline to 90 days.



Materials and Methods

▸Study design.

-An observational open-label study was conducted. The observational period lasted 3 months and 5 visits were performed: data were recorded at baseline (V0) before starting the study, at weekly intervals for 2 weeks (V1 and V2), at 30 (V3) and 90 days (V4) as final visit.

▸Patients.

-Patients of both sexes with at least 80 years old.

-All patients suffered from moderate-to-severe non-cancer chronic pain: more than 5 at movement on an 11 point numerical rating scale (NRS ≥5) from 0 to 10 was an inclusion criteria.

▸Treatments.

-The starting dose of tapentadol was 25 mg BID; in case of ineffectiveness the dosage was gradually increased only using this dose.

-All concomitant treatments for comorbidity were maintained.

▸Study evaluations

-Pain intensity at rest and at movement using patients' self-report on a 11-point NRS from 0 to 10.

-Quality of sleep using a 4-point verbal scale from 0 to 3 (0= disturbed; 1= with frequent awakenings; 2= good; 3= restful)

-Overall efficacy using a 4-point verbal scale from 0 to 3 (0= ineffective; 1= not very effective; 2= effective; 3= very effective)

-Mini Mental State Examination to measure cognitive impairment

-SF-12 quality of life questionnaire to evaluate functional health and well-being: the individual SF-12 item scores were summarized as physical and mental health composite scores.

-BADL (Activities of Daily Living) and IADL (Instrumental Activities of Daily Living) questionnaires.

-Number of responders defined as patients with 30% pain intensity reduction from baseline.

-Number and reasons of drop-out.

-Adverse effects associated with studied therapy.

Results

Thirty old patients (27F/3M) with 84.3 ± 2.9 years old (range 80-90), weight 61.9 ± 9.4 Kg (range 40-80) were enrolled. All patients had a muscoloskeletral pain (27% spondyloarthrosis and 23% LBP) and concomitant pathologies (the most frequent was cardiovascular disease).

Pain was judged continuous in 60% of all cases and mixed (nociceptive and neuropathic) in 50% of the patients recruited with mean pain intensity of 7 at movement and 4.4 at rest at the beginning of the observation.

The main dosages were: at baseline 25 mg/die; V1 (7 days) 84.6 mg/die; V2 (15 days) 112 mg/die and 136 mg/die at the end of the observational period.

A statistically significant reduction of pain score at rest (P< 0.01) and at movement (P< 0.01) was recorded after the first week of treatment with tapentadol at the daily dose of 100 mg (41% responders at V1 and 80% at the final visit). Mean (and SD) pain intensity at rest and at movement for overall pain over time are shown in Figure 1.

At baseline 32% of subjects had a good quality of sleep while 68% didn't; at the final visit the scores reverse (67% good sleep and 33% frequent waking) (Fig. 2).

Mini Mental State Examination did not change, while SF-12 significantly improved in all subscale scores: a statistically significant improvement basal-final was recorded for physical (P<0.05), mental , (P<0.01) and total SF-12 scores, as shown in Figure 3.

The BADL and IADL scores did not improved probably due to comorbidity.

At the end of the study efficacy (96%) and tolerability (83%) were judged good in the analyzed patients without any modified constipation incidence. Only 5 patients dropped due to diarrhea.

Conclusions

Comorbidity, complex therapeutic programmes and advanced age did not affect the efficacy of tapentadol in pain control and allowed a good management in fragile over eighty years old patients.

References

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2-Canonico PL et Al, Min Med 105 (Suppl. 1:6) (2014) 1-31

3-Biondi DM et Al, J Opioid Managem 11:5 (2015) 393-403