Background: Cancer pain evolve and change with disease progression. It has both a nociceptive and neuropathic component. Among strong analgesics, which still represent the cornerstone of management in cancer patients with moderate-to-severe chronic pain, tapentadol is a unique chemical entity. Due to its mechanism, we decided to evaluate efficacy and tolerability of tapentadol, a dual - opioid and noradrenergic (MOR-NRI) – central acting analgesic with effectiveness in chronic and mixed pain. The lower contribution of the opioid component also allows a reduction in adverse events µ-related. Moreover Tapentadol has a low risk of drug interactions which can be very useful in patients with complex therapeutic programmes.

Patients and methods: An observational study was conducted in adult patients, of both sexes, suffering from moderate to severe cancer pain (NRS baseline ≥4). The initial dose of tapentadol PR was 50 or 100 mg BID, in case of ineffectiveness the dosage was gradually increased up to 250 mg BID. All other analgesics, BTcP’s drugs or cancer therapies were gathered. The observation period was 3 months and 5 visits were performed. Pain intensity at rest and at movement using patients’ self-report on a 11-point NRS from 0 to 10, quality of sleep (4-point scale), DN4 (Douleur Neuropathique 4) score, Quality of life (SF-12), number and reason of drop-out were considered for the evaluation of effectiveness. All adverse events were registered and a global impression of the analgesic treatment was recorded (4-point scale).

Results: 88 patients (54%M/46%F, mean age 70 ± 10 years) suffering from cancer pain due to advanced disease (Karnofsky between 50 and 90) with mean pain intensity NRS 4.7 ± 1 at rest and 6.3 ± 1.4 at movement were enrolled. The DN4 score was positive in 27% patients. Thanks to tapentadol PR pain intensity significantly decreased from baseline (NRS -3.6 at rest and -4.8 at movement, p < 0.01). Quality of sleep and more broadly SF-12 scores improved (p < 0.01) and so did the DN4 (13% patients positive). These results were obtained with 100 and 400 mg/day: the treatment with tapentadol PR was judged effective in 56 patients (responders 67%) and the tolerability was good. The use of other analgesics including BTcP drugs was reduced during the study period.

Conclusions: Tapentadol PR was effective and well tolerated in patients with advanced cancer pain: the reduction in pain intensity at movement was strong and tolerability, even gastrointestinal, was good.