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RESEARCH ARTICLE

Zoledronic acid or Risedronic acid : Which is better in post menopausal women for osteoporosis.

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Manuscript Info

Abstract

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Introduction:-

Osteoporosis is the disease of skeletal system in which the patients have fragile bones & increased propensity to a fracture due to trivial trauma. As the age advances and senility takes on, people have increased chances of these fractures. As per WHO statistics hip fractures due to osteoporosis will increase upto 240% in women & 310 % in men by year 2050 [1]. It is thus a problem for whole world & has serious economic implications.

The sites where osteoporotic fractures are common are vertebra, hip & wrist although they can happen anywhere in body. Vertebral fractures usually are painless but patient have kyphotic deformity and leads to respiratory problems [2][3]. Fractures of hip lead to increased chances of mortality & that too within 3-6 months of injury[4].

Fracture risk is more in women as compared to men as after menopause due to hormonal deficiency, microstructural changes occur. Trabecular thinning that occurs is more pronounced in women[5].

Also larger bone size & less cortical thinning leads to a decreased incidence of these fracture in men but they also are at risk[6].

The pharmacological options for osteoporotic fractures are bisphosphonates, teriparatide, selective estrogen receptor modulators(SERMS) , donesumab(monoclonal antibody) & strontium[7].

Among them bisphosphonates are most commonly used . They reduce bone resorption by acting on osteoclasts. Oral administration requires strict adherence to regimen, fasting prior to administration & not to lie down for 30 minutes after intake as it causes oesophageal irritation[8]. But now newer studies report enteric coated risedronate oral formula that is delayed release ensuring good bioavailability when taken with food[9].

I.V zoledronic acid avoids GI manifestations but causes side effects like musculoskeletal pain, osteonecrosis of jaw, CA oesophagus, renal impairment, atypical fractures of proximal femur.

Aims and Objectives:-

Aim of the present study was to compare effect of zoledronate with risedronate in pts. of osteoporosis and side effects of these drugs in these patients.

Materials and Methods:-

This prospective study was conducted in Post graduate department of Orthopaedics Government Medical College Jammu during the period from 1st september 2013 to 31st august 2015.

Inclusion criteria:-

Post menopausal female patients were included in this study who were diagnosed as suffering from osteoporosis by DEXA scan.

Exclusion criteria:-

Male pts., pre menopausal female pts., post menopausal female pts on some other treatment modality for osteoporosis or were having fracture at the time of study or in the past 5 years.

Evaluation:-

100 post menopausal female patients were divided into 2 groups. All pts were labelled suffering from osteoporosis as per DEXA scan. In group 1 the 50 patients were given I.V zoledronic acid per year i.e twice in 2 years. In group 2 the 50 patients were given weekly 35 mg risedronic acid for a period of 2 years.

In group 1 the patients were admitted for 1 day. They had their kidney function tests checked and then only the drug was administered. All these patients were adequately hydrated with 1 RL solution given iv. Then the drug zoledronic acid was administered i.v with the rate adjusted so that the drug was administered fully in 15-30 minutes. After the i.v drug was fully administered, the patients were then discharged from the hospital. The drug was given under full medical supervision.

In group 2 the patients were prescribed oral risedronate to be taken before meals on weekly basis.

All patients in the two groups in addition to the therapy were prescribed Calcium, Vit. D and a daily exercise regimen.

Follow up evaluation:-

All patients from both groups were called for follow up on monthly basis to look for any drug related problems, muscular pain, gastritis or any fracture.

At the end of 2yrs every pt. of the study had a repeat DEXA scan.

Results:-

100 patients who were post menopausal females and established cases of osteoporosis as per DEXA scan were divided into 2 groups. Group 1 were given i.v zoledronic acid on yearly basis for 2 years whereas in group 2 weekly oral risedronic acid was given for 2 years. Along with them all patients in the study were given Calcium and Vit. D supplements and a daily exercise regimen.

Table 1

Side effects	Zoledronic acid group	Risedronic acid group
Myalgia / Arthralgia	5	2
Renal impairment	2	0
Atypical fracture of proximal femur	1	0
gastritis	0	1
Osteonecrosis of jaw	0	0
Ca oesophagus	0	0
Compliance wrt administration and side effects	Satisfactory-47 Unsatisfactory-3	Satisfactory-48 Unsatisfactory-2
Pt.s with osteopenia at the end of study	13	6
Pt.s with osteoporosis at the end of study	7	4

In group 1, 5 pts had myalgias and 2 had renal impairment during therapy. A serious complication of bisphosphonates is atypical fracture of proximal femur happened in 1 patient. It occurred 1 and half year after the therapy was started. Pt. had complained of groin pain and soreness 3 months before the fracture. Pt. was operated and fracture fixed with proximal femoral locking plate and shifted to teriparatide therapy with cessation of current treatment. No pt. in this group had osteonecrosis of jaw or CA oesophagus. 3 pts were having compliance issue with this therapy. 1 pt. having fracture and 2 due to myalgia.

In group 2, 2 pts had myalgias whereas 1 pt. suffered from gastritis on and off during the course of treatment. This pt. was given oral PPIs and antacid gels to relieve from gastritis and strict upright posture maintenance half an hour after intake of drug. No pt. in this group suffered from atypical fracture, osteonecrosis of jaw or CA oesophagus. 2 pts in this group had compliance issues, 1 having gastritis and 1 due to myalgia.

At the end of 2 years, 30 patients in group 1 and 40 in group 2 had their bmd in the normal range as per the dexa scan whereas 13 in group 1 and only 6 in group 2 were in the osteopenic range and 7 in group 1 and 4 in group 2 were still osteoporotic.

Discussion:-

Bisphosphonates are drug of choice in osteoporosis acting by inhibiting osteoclastic activity. Zoledronic i.v and Risedronic acid given orally have both given promising results. We compared the results of two bisphosphonates one given I.V the other orally for 2 years and compared as per side effects, compliance. This study shows that bisphosphonates have great efficacy in reducing vertebral and non vertebral fractures. The baseline BMD was done and pts selected for both groups before therapy and it did improved after bisphosphonate therapy.

Though osteoporosis is a disease of both sexes, we have included only post menopausal females. Disadvantage of bisphosphonate are their safety profile. Pts have side effects like myalgia, gastritis, renal impairment, atypical fracture of proximal femur. There is a decreased side effect profile of Risedronic acid as compared to Zoledronic acid.

Conclusion:-

Our study assessed efficacy of bisphosphonates in reducing risk of fractures and increasing BMD in osteoporotic pts. Our study also showed that Risedronic acid is better than Zoledronic acid in terms of decreased side effects and increased compliance.

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