

Efficacy of Bortezomib in Combination with Dexamethasone in the Treatment of Primary Multiple Myeloma

Yudi Miao*

Department of Hematology, Shaanxi Provincial People's Hospital, Xi'an 710068, Shaanxi Province, China

*Corresponding author: Yudi Miao, miaoyudi26@163.com

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Abstract: *Objective:* To study the clinical efficacy of bortezomib combined with dexamethasone in the treatment of primary multiple myeloma. *Methods:* Seventy patients with primary multiple myeloma treated in Shaanxi Provincial People's Hospital between January 2020 and January 2021 were divided into two groups, a control group and a study group, using the random number table method; 35 patients in the control group were treated with conventional treatment, and the other 35 patients in the study group were treated with bortezomib combined with dexamethasone. The patients' clinical outcomes, clinical indices, satisfaction, and adverse reactions were compared between the two groups. *Results:* There were significant differences ($p < 0.05$) in the indices between the two groups of patients treated with different treatment modalities for primary multiple myeloma. *Conclusion:* The use of bortezomib combined with dexamethasone for patients with primary multiple myeloma can effectively improve the treatment outcomes, clinical indices, patient satisfaction, and adverse reactions; hence, it is worthy to be widely promoted in clinical practice.

Keywords: Bortezomib combined with dexamethasone; Primary multiple myeloma; Clinical efficacy

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1. Introduction

Multiple myeloma is the most common type of malignant plasma cell disease, also known as myeloma or plasma cell myeloma. Multiple myeloma is characterized by the malignant proliferation of monoclonal plasma cells and the secretion of large amounts of monoclonal immunoglobulins [1-3]. The uncontrolled proliferation of malignant plasma cells, the extensive infiltration, and the appearance and deposition of large amounts of monoclonal immunoglobulins lead to the suppression of normal polyclonal plasma cells and polyclonal immunoglobulin secretion, resulting in a series of clinical manifestations, such as extensive bone destruction, recurrent infections, anemia, hypercalcemia, hyperviscosity syndrome, and renal insufficiency [4-8]. The aim of this study was to analyze the clinical efficacy of bortezomib in combination with dexamethasone for patients with primary multiple myeloma.

2. Methods

2.1. Study population

Seventy patients with primary multiple myeloma admitted to Shaanxi Provincial People's Hospital from January 2020 to January 2021 were selected and divided into two groups using the random number table method. All 35 patients in the control group were treated conventionally, and the other 35 patients in the

study group were treated with bortezomib combined with dexamethasone. In the control group, there were 17 male patients and 18 female patients, whereas in the study group, the patients' age ranged from 27 to 69, with a mean age of 49.21 ± 1.93 , of whom 19 were male and 16 were female. The demographic difference between the two groups was not statistically significant ($p > 0.05$) and was comparable. This study was approved by the ethics committee of our Shaanxi Provincial People's Hospital. The patients and their families were informed of the study and signed the informed consent form.

Inclusion criteria: (1) diagnosed with indications of primary multiple myeloma [9,10]; (2) able to communicate normally.

Exclusion criteria: (1) patients with malignancy; (2) patients with cognitive impairment; (3) those with contraindications to medication and poor compliance.

2.2. Study design

In the control group, conventional treatment was used: vincristine (Qilu Pharmaceutical [Hainan] Co., Ltd., State Pharmacopoeia H20093078) was administered intravenously at a dose of 25-30 mg/m² per week; pirarubicin (Shenzhen Wanle Pharmaceutical Co., Ltd., State Pharmacopoeia H10930106) was dissolved in 5% dextrose injection; dexamethasone (Guangdong Nanguo Pharmaceutical Co., Ltd., GZP H44024618) was administered orally, with a starting dose of 0.75-3.00 mg (1-4 tablets) once, 2-4 times a day for adults, and a maintenance dose of approximately 0.75 mg (1 tablet) a day, depending on the condition.

The study group received bortezomib combined with dexamethasone: 1.3 mg/m² of bortezomib (Nanjing Zhengda Tianqing Pharmaceutical Co., Ltd., State Pharmacopoeia H20183401) was injected as a single injection twice a week; the dosage of dexamethasone was the same as that of the control group.

2.3. Outcomes

- (1) The treatment outcomes of the two groups were compared using the European Group for Blood and Marrow Transplant (EBMT) response criteria: complete response, partial response, minimal response, no change, and progressive disease.
- (2) The hemoglobin, M protein, beta-2 microglobulin, and serum creatinine levels of the patients were taken before and after treatment for comparison between the two groups.
- (3) The patients were also surveyed using a self-made satisfaction questionnaire with a total score of 10, with very satisfied being 8-10, satisfied being 4-7, and unsatisfied being less than 3. Satisfaction = (very satisfied + satisfied)/total*%.
- (4) The adverse reactions of the patients were also compared between the two groups.

2.4. Statistical analysis

The data were processed using SPSS 20.0. T-test was performed for the two groups of patients, and chi-square (χ^2) test was performed for the count data, which were expressed in percentage (%). $p < 0.05$ was considered statistically significant.

3. Results

3.1. Clinical outcomes

There was a significant difference in the clinical outcomes observed between the study group and the control group ($p < 0.05$), as shown in **Table 1**.

Table 1. Comparison of clinical outcomes between the two groups of patients (n/%)

Group	Complete response	Partial response	Minimal response	No change	Progressive disease	Efficacy
Study group	13 (37.14)	16 (45.71)	5 (14.29)	1 (2.86)	0 (0.00)	34 (97.14)
Control group	9 (25.71)	11 (31.43)	4 (11.43)	4 (11.43)	2 (5.71)	29 (82.86)
χ^2						3.9683
<i>p</i>						0.0464

3.2. Clinical indices before and after treatment

Before treatment, there was no significant difference in the two clinical indices between the two groups of patients ($p > 0.05$). After treatment, the clinical indices in both the study group and the control group saw a significant improvement ($p < 0.05$); the comparison of the clinical indices between the two groups showed that both clinical indices in the study group were significantly better than those in the control group ($p < 0.05$), as shown in **Table 2**.

Table 2. Comparison of patients' clinical indices before and after treatment between the two groups ($\bar{x} \pm s$)

Group	Hemoglobin (g/L)		M protein (g/L)	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Study group (n=35)	84.52 ± 13.26	105.67 ± 22.57	56.50 ± 1.100	17.76 ± 5.50
Control group (n=35)	84.44 ± 13.58	94.42 ± 23.18	56.50 ± 1.52	41.67 ± 12.53
<i>t</i>	0.0249	2.0572	0.0000	10.3372
<i>p</i>	0.9802	0.0435	1.0000	0.0000

Group	Beta-2 microglobulin (m/L)		Serum creatinine (mol/L)	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Study group (n=35)	4.29 ± 0.91	2.31 ± 0.78	103.62 ± 14.31	75.22 ± 13.21
Control group (n=35)	4.35 ± 0.89	3.41 ± 1.62	105.41 ± 14.32	119.41 ± 32.41
<i>t</i>	0.2789	3.6194	0.5231	7.4697
<i>p</i>	0.7812	0.0006	0.6026	0.0000

3.3. Patient satisfaction

The difference in patient satisfaction when comparing the study group with the control group was statistically significant ($p < 0.5$), as shown in **Table 3**.

Table 3. Comparison of patient satisfaction between the two groups (n/%)

Group	Number of cases	Very satisfied	Satisfied	Unsatisfied	Level of satisfaction
Study group	35	28 (80.00)	7 (20.00)	0 (0.00)	35 (100.00)
Control group	35	20 (57.14)	9 (25.71)	6 (17.14)	29 (82.86)
χ^2					6.5625
<i>p</i>					0.0104

3.4. Adverse reactions

The adverse reactions observed in the study group were significantly lower than those in the control group ($p < 0.05$), as shown in **Table 4**.

Table 4. Comparison of adverse reactions between the two groups (n/%)

Group	Number of cases	Fatigue	Infection	Diarrhea	Incidence rate
Study group	35	1	0	0	1 (2.86)
Control group	35	2	3	1	6 (17.14)
χ^2					3.9683
p					0.0464

4. Discussion

Myeloma, also known as plasma cell myeloma, is a malignant tumor of the hematological system [11-15]. Currently, its etiology is unclear, and data from studies have confirmed that there is a relationship between the development of myeloma and a number of factors. These high-risk factors include ionizing radiation, which can lead to a high incidence of myeloma [16-18], long-term chronic antigenic stimulation, which can also lead to an increased incidence of myeloma, genetic factors, which have a relationship with the occurrence of myeloma, and the activation of oncogenes, such as c-MYC, which is also a known risk factor for carcinogenesis. The main treatment for multiple myeloma is systemic chemotherapy with VAD regimen (vincristine, Adriamycin, and dexamethasone), MP regimen (melphalan and prednisolone), and bortezomib-containing regimens [19-21], in addition to thalidomide, lenalidomide, and other drugs. Bortezomib-containing regimen, as the preferred regimen for the treatment of multiple myeloma, has little toxicity and is by far the most effective. The difference between the two groups of patients treated with different modalities of treatment for primary multiple myeloma was statistically significant ($p < 0.05$).

In conclusion, by administrating bortezomib in combination with dexamethasone to patients with primary multiple myeloma, it can effectively improve the treatment outcomes and clinical indices of patients; thus, it is worthy of wide promotion in clinical practice.

Disclosure statement

The author declares no conflict of interest.

References

- [1] Yu JS, Li FM, Situ XH, 2020, Study on the Nursing Response of Bortezomib Combined with Dexamethasone in the Treatment of Multiple Myeloma. *Massage and Rehabilitation Medicine*, 11(2): 66–67.
- [2] Yu W, 2020, Clinical Efficacy Analysis of Bortezomib Combined with Dexamethasone in the Treatment of Patients with Multiple Myeloma. *Contemporary Medicine*, 26(35): 149–151.
- [3] Lu J, Zhu XJ, 2020, Clinical Efficacy and Toxic Side Effects of Bortezomib Combined with Cyclophosphamide and Dexamethasone in the Treatment of Multiple Myeloma. *Hebei Medicine*, 26(4): 537–540.
- [4] Ding H, 2020, Clinical study on the Treatment of Phlegm-Stasis Paralysis Type Primary Multiple Myeloma with Huachansu Tablets Combined with TD Regimen, dissertation, Nanjing University of Traditional Chinese Medicine.

- [5] Wang Y, Lv G, Zhang Y, et al., 2020, Cost and Efficacy Analysis of Bortezomib, Dexamethasone and Thalidomide Regimen in the Treatment of Multiple Myeloma. *Modern Medical Oncology*, 28(4): 622–625.
- [6] Lv N, Wang H, Liu F, et al., 2020, Clinical Efficacy of Bortezomib Combined with Dexamethasone in the Treatment of Patients with Multiple Myeloma. *International Journal of Medicine and Health*, 26(1): 108–109.
- [7] Yang F, Qing S, Xu F, et al., 2020, Evaluation of the Efficacy and Safety of Bortezomib + Cyclophosphamide + Dexamethasone Weekly Regimen Versus Conventional Regimen in the Treatment of Primary Multiple Myeloma. *Anhui Medicine*, 24(11): 2295–2298.
- [8] Liu S, Liu Y, 2021, Clinical Efficacy of Melphalan Tablets in Combination with Bortezomib and Dexamethasone in the Treatment of Multiple Myeloma. *Journal of Clinical Rational Drug Use*, 14(24): 86–88.
- [9] Wang MJ, Yang LH, Yan QX, 2021, Efficacy of Bortezomib Combined with Cyclophosphamide and Dexamethasone in the Treatment of Multiple Myeloma and the Effects on Patients' Renal Function Indicators and Adverse Effects. *Hebei Medicine*, 27(5): 864–869.
- [10] Huang Z, Yang C, Liang I, et al., 2022, Evaluation of the Efficacy of Recombinant Human Erythropoietin in Combination with Bortezomib and Dexamethasone in the Treatment of Multiple Myeloma in the Elderly. *Chinese Contemporary Medicine*, 29(1): 39–42 + 46.
- [11] Ge Y, Ding X, Gao L, 2020, Efficacy and Safety Analysis of Bortezomib Combined with Dexamethasone in the Treatment of Multiple Myeloma. *Medical Theory and Practice*, 33(1): 65–66.
- [12] Guo ZJ, Yang Q, 2020, Efficacy and Safety Analysis of Bortezomib Combined with Dexamethasone in the Treatment of Patients with Multiple Myeloma. *Primary Care Forum*, 24(22): 3147–3148.
- [13] Zhang G, 2020, Clinical Efficacy of Bortezomib Combined with Dexamethasone in the Treatment of Patients with Multiple Myeloma. *China Health Care Nutrition*, 30(8): 95.
- [14] Xiao J, 2020, Evaluation of the Efficacy of Cyclophosphamide Combined with Injectable Bortezomib and Dexamethasone in the Treatment of Multiple Myeloma. *Northern Pharmacology*, 17(7): 163–164.
- [15] Tang SL, Li J, 2021, An Investigation of the Efficacy of Bortezomib and Dexamethasone Combined with Hemodialysis in the Treatment of Multiple Myeloma Nephropathy. *Contemporary Medicine Series*, 19(18): 110–112.
- [16] Guo T, Ji D-M, 2020, Efficacy and Safety of Different Doses of Bortezomib Combined with Dexamethasone and Thalidomide in the Treatment of Multiple Myeloma. *Health Care Medicine Research and Practice*, 17(4): 42–46.
- [17] Mi HY, Yang QA, Sun YQ, 2021, Clinical Effects of Bortezomib Combined with Dexamethasone in the Treatment of Multiple Myeloma in the Elderly. *Chinese Contemporary Medicine*, 28(13): 12–16.
- [18] Huang G, Liao JJ, Huang JX, et al., 2020, Clinical Efficacy and Safety of Bortezomib + Cyclophosphamide + Dexamethasone in the Treatment of Multiple Myeloma. *China Modern Drug Application*, 14(10): 159–160.
- [19] Ma YQ, Yang XT, 2020, Effectiveness of Bortezomib in Combination with Adriamycin and Dexamethasone in the Treatment of Multiple Myeloma. *Henan Medical Research*, 29(21): 3932–3934.
- [20] Lei LH, He D, Lin J, et al., 2020, Effects of Bortezomib Combined with Dexamethasone on Bone Metabolism and Immune Function in Patients with Multiple Myeloma. *Journal of Practical Cancer*, 35(6): 917–920.

[21] Shen M, Huang Z, Zhang J, et al., 2021, Clinical Observation on the Efficacy of Bortezomib Maintenance Therapy in 25 Patients with Non-Transplanted Multiple Myeloma. *Chinese Journal of Experimental Hematology*, 29(1): 131–136.

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