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Relation between the Short Term Health Related Quality of Life and Various Types of Medical Treatment in Patients with Idiopathic Chronic Thrombocytopenia

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Abstract

Background: Chronic Idiopathic Thrombocytopenic Purpura (ITP) is an autoimmune disorder characterized by a low platelet count due to reduced production and higher destruction of the platelets. Therapy is aimed at increasing the patient's platelet count to safe levels and includes a wide variety of treatments, which has a large impact on the patient's quality of life. Health Related Quality of Life (HRQoL) is one of the most important factors to evaluate the efficacy of the treatment. This study was conducted to compare the effect of the various types of treatment on HRQoL in ITP patients.

Materials and Methods: Ninety under 25 year-old patients were included in this cross-sectional study. All patients had active disease with platelet count of less than 120,000/mm3. The patients were divided into 3 treatment groups: 1- Intravenous immunoglobulin (IVIg) treatment, 2- various corticosteroids treatments and 3- Immunosuppressive treatments, and filled-out a validated "quality of life" questionnaire.The HRQoL was calculated according to the collected information such as well-physical activity, gynecologic problems, bleeding disorders, response to treatment, side effects and social interactions.

Results: Ninety patients were enrolled, consisting of 38 male and 52 females. The mean age of the patients was 19.73±4.02 years. The mean total score of HRQoL was 21.8±9.1. We did not find any significant difference in HRQoL total score among treatment groups (p=0.129).

Conclusion: HLQoL did not differ among treatment protocols and it seems that other factors are more important in influencing quality of life among ITP patients.

Keywords: Purpura, thrombocytopenic, idiopathic, quality of life, immunoglobulins, corticosteroids, immunosuppressive agents

Introduction

Idiopathic Thrombocytopenic Purpura (ITP) is an autoimmune disorder characterized by antibody-mediated acceleration of platelet destruction and suboptimal platelet production which leads to reduced peripheral blood platelet counts. The etiology of ITP is poorly understood. The estimated annual incidence of adult ITP ranges from 0.6 to 6.6 cases per 100,000 adults with a prevalence of 10 to 100,000 and a female to male ratio of nearly two to one [1]. Chronic ITP (CITP) refers to patients with a platelet count fewer than 30,000 for more than 6 months with standard therapy, which is seen in 10-20% of the affected children [2]. There are studies estimating that five year mortality rates for CITP patients is near 2.2% for patients under 40 years of age and 47.8% for patients older than 60 [3]. Initial therapy for ITP consists of various combinations of corticosteroids, intravenous immunoglobulin (IVIg) and immunosuppressive drugs. Splenectomy is considered if these therapies fail [4, 5].

Morbidity and mortality among CITP patients are major concerns. As World Health Organization (WHO) describes, Patients Reported Outcomes (PRO) such as Health Related Quality of Life (HRQoL) are among the most important factors in evaluating patients' improvement. PRO is not a simple measure

of symptoms but should also include an assessment of function (e.g. physical, emotional, social and sexual) and health-related quality of life. Thus, HRQoL can demonstrate the effect of the disease and its treatment on daily mental and physical activities [6, 7]. ITP has a negative impact on patients' HRQoL [1, 8]. In a recent study, lower platelet counts were consistently associated with worse HRQoL; fatigue, muscle cramps, and psychiatric problems such as depression [8]. However, laboratory indices such as platelet count and coagulation times are not appropriate enough to measure the patients HRQoL;and in CITP, improvement in physical activity and lower adverse effects of the treatments are the main factors influencing HRQoL [1].

Mnimum information about the difference between treatment protocols of ITP regarding the quality of life, especially in Middle Eastern patients, encouraged us to conduct this study to assess the HRQoL in ITP patients undergoing various types of medical treatment.

Materials and Methods

Patients

In this analytical cross-sectional study, 90 active, 13 to 25-year-old CITP patients, which were referred to Rasoul -Akram and Ali-Asghar Children's hospitals, were enrolled. Patients with platelet count less than 120,000/mm3 and signs and symptoms of ITP undergoing treatment and monitoring were eligible to participate. Patients with another disability or chronic disease were excluded. Included individuals were asked to fill a validated HRQoL questionnaire consisting of 10 questions assessing sleep problems, gynecologic disorders, bleeding, substantial treatment, drug adverse effects, as well as physical and mental health, social activity and overall life quality. The scale is ranged between zero (best) and 34 (worst), with Standardized Cronbach's Alpha of 81.6%. Demographic data and laboratory results such as complete blood count were also extracted using a defined checklist.

We divided the participants into three groups based on their treatment regimen (IVIg, corticosteroids or immunosuppressive drugs) to find a probable difference of HRQoL among these groups. For further analyses, all individuals were also divided into two groups regarding their splenectomy status.

Statistical methods

All data were analyzed using SPSS version 20 (Chicago, Illinois, USA). We computed the reliability of the questionnaire by calculating Cronbach's Alpha rliabilitycoefficient. Qualitative data were expressed as percent and quantitative data as mean ± SD. Before analyzing them, all quantitative data were tested for normal distribution by Kolmogorov-Smirnov test. Statistical tests such as student's t-test, Chi-square , Mann-Whitney-U, one-way ANOVA and Kruskal-Wallis were used. A p-value less than 0.05 was considered as significant.

Ethical issues

This study was approved by the ethical committee of the Tehran University of Medical Sciences. All patients or their next of kin were aware of their presence in the study and verbal consent was taken. We kept all patients' personal information confidential.

Results

TBaseline characteristics

Ninety patients were enrolled, consisting of 38 male and 52 females. The mean age of the patients was 19.73±4.02 years. No significant age difference was seen between genders (p=0.839).

Table1: Complete blood count in male and female subjects; no significant difference was seen between genders.

	Total	Male	Female	p
Age (year)	19.73±4.02	19.36±4.09	19.8±4.01	0.839
WBC (/mm^3)	7552.93	7255.88±2373.61	7763±3135.57	0.429
Hg (mg/dl)	12.1276	12.20±2.22	12.06±1.26	0.749
Plt (10^5/mm)	48996.39	45.81±35.06	51.12±3.98	0.527

WBC: White Blood cell count; Hg: hemoglobin;
plt: platelet count.

Also no significant difference was seen between gender regardig laboratory results as shown in table 1(p>0.05).

Treatment

All 90 patients were under medical treatment. The most common treatment was IVIG (66 patient, 73.3%), following by prednisolone (48 patients, 53.3%), and danazole (11 patients, 12.2%). We divided the patients into 3 groups; IVIG only group (37 patients, 41.1%), Corticosteroid only or added group (39 patients, 34.3%) and other treatments group (14 patients, 15.5%). No significant difference was seen in mean age between these groups (P=0.229). In contrast, there was gender preference among these groups as demonstrated in table 2(p=0.041). In addition, no significant difference was found in hemoglobin level (p=0.335), white blood cell count (p=0442) and platelet count (p=0.527) among different treatment methods.

Health related quality of life questionnaire and analyses

All patients filled-out the HRQoL questionnaire. The detailed results are demonstrated in table 3. The mean total score was 21.8±9.1. No significant difference was found between male (22.44±8.04) and female (21.26±9.97) subjects (p=0.582).

We also did not find any significant difference in HRQoL total score among treatment groups (p=0.129). Furthermore, no significant difference was found between each two groups (Table 4). After further analysis, we did not found any significant correlation between HRQoL and white blood cell count (p=0.072), hemoglobin level (p=0.566) and platelet count (p=0.644).

Splenectomy

We also divided our patients into two groups considering their splenectomy status. Ninteen patients (21.1%) had a positive history of splenectomy. The results show that platelet count was significantly lower in splenectomy positive patients (29178±6719 /mm3 vs. 54789±4784 / mm3, p=0.009); however, no significant difference was found in age (p=0.181), white blood cell count (p=0.155) and hemoglobin levels (p=0.544).

No significant difference was found in HRQoL between patients with positive and negative history of splenectomy (23.12±9.69 vs. 21.44±8.99 respectively, p=0.515). In addition, there were no significant treatment preference between these two groups of patients (p=0.345).

Discussion

This study conducted to study the HRQoL in CITP patients referred to our hospitals and compare them by their treatment type. Based on our results, the type of treatment does not have any effect on the patients' HRQoL.

In our study, the mean age was near 20 years, which also did not show any correlation with HRQoL. Cines et al. reported that HRQoL in ITP patients is variable among age groups. As a fact, hemorrhage is the most effective factor in medical and psychological aspects among ITP patients. Aging makes the patients more prone to hemorrhage, so it seems that higher age should be associated with lower quality of life [9].

The male to female ratio in our study was approximately 4/5. This result resemble the other studies [1, 9], which have reported a higher female

Table2: Cross tab of gender and treatment groups. Gender preference is seen.

		Treatment group			
		IVIG and Corticosteroid Immuno- modulator	IVIG & Corticosteroid	IVIG only	Total
Gender	Male	10	16	12	38
	Female	4	23	25	52
	Total	14	39	37	90
		p= 0.047			

Table3: Detailed demonstration of HRQoL questionnaire results in CITP patients; no significant different was found in any components.

	n	Total	male	female	p
Q1 (History of bleeding)	90	1.23±0.97	1.39±0.916	1.12±1.003	0.279
Q2 (Treatment effectiveness)	90	1.44±0.901	1.63±0.786	1.31±0.961	0.324
Q3 (Physical fatigue)	90	1.33±0.948	1.47±0.893	1.23±0.983	0.243
Q4 (limitation in physical act)	86	6.39±2.79	6.50±2.72	6.32±2.86	0.18
Q5 (fear of disease)	79	7.00±3.15	7.16±2.97	6.86±3.32	0.306
Q6 (depression feelings)	90	1.18±0.99	1.32±0.962	1.08±1.007	0.239
Q7 (change in occupation)	7¶	2.00±0.577	2.00±0.879	2.00±0.816	n/a¶
Q8 (limitation in social act)	90	1.58±0.821	1.63±0.786	1.54±0.851	0.93
Q9 (Change in period bleeding)*	52	0.68±0.956	n/a*	0.68±0.956	n/a*
Q10 (self rating of QoL)	90	0.78±0.98	1.05±1.012	0.58±0.915	0.476

Q: Question; N/A: not applicable. (*: no comparison can be made by men, because of the low rate of answers, no comparison was made)

proportion. As found in our study, no significant relation between HRQoL and gender have been reported [10]. This indicates that ITP severity is not affected by the sex.

In previous studies, the effect of complete blood count on ITP patients HRQoL has also been evaluated [1, 9-10]. In our study, the type of treatment did not affect any counts. Furthermore no correlation was found between HRQoL and the blood counts which indicates that the quality of life cannot be elevated by changing or adding a treatment. Cooper et al. have evaluated the changing trend of HRQoL in 3 months intervals until 2 years. They found that HRQoL does not increase with the improvement of platelet count. However, after a year of any treatment, it will start to progress [11]. We can summarize that the HRQoL is not related to platelet count or the type of treatment.

After overall evaluation of the patients, we divided the patients into 3 major treatment groups and compared the HRQoL scores. We did not found any difference between groups. Our results are most comparable with Mathias et al study [1], which reported similar results; however, there were significant difference in patients' perspective of treatment efficacy. Furthermore, our study showed that patients undergoingsplenectomy have lower platelet counts, but no difference in HRQoL score. This result might be ralaated to the recommendations of splenectomy in more severe ITP patients; however, the intervention itself mmight affect the quality of life. More studies with before and after splenectomy evaluation is recommended [8].

It seems that choosing a treatment method is a decision making process, based on patients' view, HRQoL, psychological factors, platelet counts and medical symptoms; because the quality of life in CITP patients is not just affected by laboratory tests. Some of the factors such as bleeding fears and employment instability, which have never been an issue in medical evaluation are proven to be important in patients' treatment. On the other hand, treatment usually takes time to make gross effects and all these factors can influence the quality of life by direct and indirect means.

Conclusion

Our study shows that HRQoL total score does not differ among different types of treatment among CITP patients, and is more affected by signs, symptoms, and psychological factors. Furthermore, our results suggest that splenectomy might not be an effective way to increase HRQoL among these patients.

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