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Research Article

IMPACT MONITORING OF LOW AND HIGH DEXAMETHASONE DOSES ON COVID-19 OUTCOMES IN HODEIDAH, YEMEN: A PHARMACOEPIDEMIOLOGICAL STUDY

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ABSTRACT

Objectives: The study aimed to describe the pharmacoepidemiological properties of high and low dexamethasone doses on patients from COVID-19 in Hodeidah, Yemen.

Methodology: A randomized clinical trial included 192/323 patients with COVID-19 (28/49 cases in the first wave 2020 and 164/274 cases in the second wave 2021), aged from 3 to 80 years old, confirmed by real time-polymerase chain reaction. All patients were admitted in the isolation department, Center of Tropical Medicine and Infectious Diseases, AL Thawara Public Hospital Authority, Hodeidah, Yemen. 28 patients received high dose of dexamethasone (20–10 mg daily for 10 days) with standard care in the first wave and 164 patients received low dose of dexamethasone (6–8 mg daily for 10 days) in the second wave with standard care.

Results: The results showed non-significant differences between the impact of dexamethasone in both waves with different doses of dexamethasone ($X2$: 1.70; p=0.91). On the other mean, the case fatality rate (CFR) in the first wave with high dose was 10.71% and CFR of the second wave with low dose was 22.29%. While the results showed significant differences between high dose and low dose group with mechanical ventilator "mechanical ventilation (MV)" ($X^{2:}$ 7.10; p=0.0076), the CFR of patients with MV and high dose was 37% and CFR of the second wave with low dose was 77% In addition, all admitted cases had acute respiratory distress syndrome and the onset date of symptom was 2 weeks before hospitalization. Old age, chronic diseases, and co-infection may be contributing factors to effect on dexamethasone efficacy and excess mortality among COVID-19 patients.

Conclusion: The study assessed the effectiveness of dexamethasone in high and low dose in treating patients hospitalized with COVID-19 in Hodeidah, Yemen and found difference between mortality and recovery outcomes with high and low dose where the high doses of dexamethasone had good outcome for critical cases with MV.

Keywords: COVID-19, Dexamethason, Pharmacoepidemiology, Yemen

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INTRODUCTION

Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by a single-stranded positive-sense RNA virus that was first isolated in December 2019 after it emerged in Wuhan, China [1,2]. In Yemen, the first case was registered on April 10, 2020 in Hadhramout [3], with further cases later identified in other parts of the country as the disease spread. There are no specific generally accepted therapies for the COVID-19. The COVID-19 ranges from asymptomatic disease to mild case, severe pneumonia, and critical case namely acute respiratory distress syndrome (ARDS) or organ failure, and death [4]. A small percentage of COVID-19 patients require hospitalization and intensive care unit (ICU). Patients with radiological finding based on involvement of COVID-19 have a spectrum of presentations that range from scattered ground-glass infiltrates to diffuse infiltrates with consolidation. Patients with the latter radiological finding have severe hypoxemia and usually require mechanical ventilation (MV). In addition, some patients develop multiorgan failure, deep venous thrombi with pulmonary emboli, and cytokine storm syndrome [5]. Pharmacoepidemiology is the study of interactions between clinical drugs using and human populations (effect of drugs on outcomes), also for investigation the real conditions of life, benefits, risks, and use of drugs and to improve the"rational drug use [6,7]. Therefore, what is the perfect dose of dexamethasone impact on COVID-19 outcome? On the other mean, our study aimed to describe the pharmacoepidemiological properties of high and low dexamethasone dose on patients with COVID-19 in Hodeidah, Yemen.

METHODOLOGY

Study design

The research study utilized a randomized clinical trial (RCT) to monitor the effect of different doses of dexamethasone on patients with COVID-19 through analyzing data from 192/323 patients admitted to the isolation department of the Center of Tropical Medicine and Infectious Diseases (CTMID) at AL Thawara Public Hospital Authority, Hodeidah, Yemen.

Study area and settings

The study took place in COVID-19 isolation department of CTMID which affiliated to Al-Thawara Public Hospital Authority, Hodeidah, Yemen. The CTMID was built with support from the World Bank's International Development Association, and in partnership with the United Nations Development Programme and the Social Fund for Development to reduce pressure on Al-Thawra Public Hospital Authority which regarded the main medical services provider in Hodedah governorate that often threatened by disease and epidemics and received cases from the governorate itself and other adjacent governorates such as Hajjah, Al-Mahweet, and Raymah governorates. Several outbreaks were reported in study area, namely cholera, diphtheria, malaria, and dengue

fever were reported in Yemen [8-13]. The COVID-19 was confirmed in this area based on several studies [14-19].

Sample size and sampling method

The study included a total of 323 patients with confirmed COVID-19. Among them, 49 cases were from the first wave in 2020 and of severe cases and 274 cases were from the second wave in 2021. The patients were selected from those admitted to the isolation department of the CTMID at Al Thawara Public Hospital Authority in Hodeidah, Yemen. Patients admitted to the CTMID during the specified periods were included in the study using the Convenience Sampling Method. The sample consisted of 192/323 patients with COVID-19, divided into two groups: 28 patients who received a high dose of dexamethasone (10–20 mg daily for 10 days) in the first wave standard care and 164 patients who received a low dose of dexamethasone (6–8 mg daily for 10 days) in the second wave standard care.

Ethical considerations

The study adhered to ethical guidelines, ensuring patient confidentiality and privacy. Ethical approval was yielded from the relevant institutional review board or ethics committee of the Center for Tropical Medicine and Epidemiology Studies, Hodeidah University that is academic, research and applied center before conducting the research.

Participants

Participants groups

The study participants comprised patients aged between 3 and 80 years old who tested positive for COVID-19 using real-time polymerase chain reaction (RT-PCR). All participants were admitted to the isolation department of CTMID. The groups were divided into two groups. The first group in first wave (2020): 28 patients received high-dose dexamethasone (20–10 mg daily for 10 days). The second group in second wave (2021): 164 patients received low-dose dexamethasone (6–8 mg daily for 10 days).

Inclusion criteria

The inclusion criteria included (1): Patients with confirmed COVID-19 diagnosis through RT-PCR.; (2): Age range of 3–80 years old; (3): Admitted during either the first wave (2020) or second wave (2021) of COVID-19 cases; (4): Patients who had received dexamethasone with standard care for 10 days (full dose); (5): Patients whom onset of infection was no later than hospital admission.

Exclusion criteria

The exclusion criteria included (1) Patients who received un-adjusted/less than approved full dose of dexamethasone who received care at hospitals <10 days, to ensure all individuals had a nonzero probability of receiving treatment (2) Patients who received dexamethasone for <10 days as a minimum treatment regimen; (3) Patients who were died within 48 h of admission, to avoid immortal time bias.

Data collection methods

The data were collected based on RCT design, qualified team monitored daily the patient charts and recorded the data in medical files. Relevant information, such as patient demographics, RT-PCR results, treatment received (dexamethasone dose), and disease severity, were reported from patients directly.

Data analysis

Statistical analysis was carried out on the collected data to compare the outcomes between the two groups (high dose versus low dose of dexamethasone). The analysis aimed to determine any differences in disease progression, severity, and patient outcomes based on the dose of dexamethasone received.

RESULTS

Characteristics of patients

Table 1 provides an overview of the sociodemographic characteristics of severe and critical COVID-19 patients in Hodeidah, Yemen. Table 1 displayed variables such as gender, age, and residency. In terms of gender, the data showed that 85.71% of males patients and 14.28% of females patients. The age distribution revealed that patients <15 years old accounted for 3.57%, while the majority of patients were in the 30–49 age group (32.14% in the first wave and 27.43% in the second wave). The table also indicated that the residency of the patients was 67.85% from rural areas and 32.14% from urban areas.

Table 1: General sociodemographic data of severe and critical COVID-19 patients in Hodeidah, Yemen (n=192)

Variables	(n)	(%)	(n)	(%)
Gender				
Male	24	85.71	121	73.78
Female	4	14.28	43	26.21
Total	28	100	164	100
Age				
<15	1	3.57	1	0.60
15–29	2	7.14	6	3.65
30–49	9	32.14	45	27.43
50–59	9	32.14	26	15.38
60+	7	25	86	52.43
Total	28	100	164	100
Residency				
Urban	9	32.14	50	30.48
Rural	19	67.85	114	69.51
Total	28	100	164	100

*Significant (p<0.05)

Association of factors with severe and critical COVID-19 morbidity

Table 2 examined the association between co-morbidities, co-infections, and the morbidity and mortality of severe and critical COVID-19 patients. Table 2 presents the presence of various risk factors and their relationship with different outcomes. For example, diabetes was observed in both waves of the study, with 5/28 cases (17.85 5) in the first wave and 17/164 cases (10.36) in the second wave associated with morbidity. The presence of diabetes combined with heart diseases or asthma also contributed to morbidity and mortality. Other risk factors, such as hypertension, chronic renal failure, obesity, and respiratory conditions, showed varying degrees of association with severe outcomes. This table highlights the importance of considering underlying health conditions when assessing COVID-19 severity and prognosis.

Association of factors with severe and critical COVID-19 mortality

Table 3 assesses the impact of high and low doses of dexamethasone on overall COVID-19 outcomes. Table 3 presents the number and percentage of deaths and recoveries among patients receiving different doses of dexamethasone (N: 192; severe and critical cases). In the high-dose group, there was only 3/28 (10.71%) of patients died (n: 3; critical cases), while 25/28 (89.28%) of the total patients included in the study were recovered (n: 25; 19 severe of cases and 6 of critical cases). In the low-dose group, the case fatality rate (CFR%) was 35/164 (21.47%) (n: 35; critical cases) while 129/164 (78.52%) of patients recovering (n: 129: 119 of severe cases and 10 of critical cases). The study showed that there was no statistically significant difference in outcomes between high and low doses of dexamethasone among COVID-19 admitted patients ($X^{2:}$ 1.70; p=0.91).

Table 4 focuses specifically on the impact of high and low doses of dexamethasone on critical illness (n: 54/192), as indicated by the need for MV. Table 4 displays the number and percentage of deaths and recoveries among patients receiving different doses of dexamethasone. In the high-dose group, 3/9 patients (33.33%) were died, while 6/9 patients (66.66%) were recovered. In contrast, the low-dose group had a higher mortality rate of 35/45 patients (77.77%) and a lower recovery rate of 10/45 patients (22.22%). The analysis revealed a significant difference in outcomes between high and low doses of dexamethasone in relation to critical illness and the need for

Table 2: Association of factors with severe and critical COVID-19 morbidity and mortality (n=192)

Risk Factors	First wave (low dose of dexamethasone)			Second wave (High dose of dexamethasone)		
	Morbidity	Mortality	MV Recovered	Morbidity	Mortality	MV Recovered
Diabetes	5			17	7	
Diabetes with Heart Diseases	3		1	2		
Diabetes - Heart – Asthma	1	1				1
Diabetes – Hypertension				1		1
Diabetes - Heart – Hypertension				1		
Diabetes with Obesity				1		
Diabetes with Asthma	1	1	1			
Heart Diseases	3			3	2	
Heart Diseases with Asthma	1			1		
Asthma	2			2	1	
Heart and Hypertension				2		
Hypertension	1	1	1	14	2	1
Chronic Renal Failure	1			6	1	
Chronic Renal Failure and Hypertension				1		
Chronic Renal Failure and Hypertension				2		
Chronic Renal Failure and Asthma				1		
Obesity				2		
Obesity - Heart Disease – Hypertension				2	1	1
Tuberculosis	1			0		
Thyroid Gland				10		
ICVA				1		
Burn				1		
Psychiatric				1		
Hepatitis C				1	1	
Non	9		2	92	20	6
Total	28	3	5	164	35	10

Table 3: Impact of high and low doses of dexamethasone on all COVID-19 outcome in Hodeidah, Yemen (n=192)

Doses	Death		Recovery		Total	X^2	p-value
	N	%	n	%			
High dose	3	10.71	25	89.28	28	1.7015	0.192
Low dose	35	21.47	129	78.52	164		
Total	38		154		192		

Table 4: Impact of high and low doses of dexamethasone on critical illness (receiving MV) COVID-19 outcome in Hodeidah, Yemen (n=54/192)

Doses	Death		Recovery		Total	X^2	p-value
	n	%	n	%			
High dose	3	33.33	6	66.66	9	7.1053	0.007686
Low dose	35	77.77	10	22.22	45		
Total	38		16		54		

MV ($X^{2:}$ 7.10; p=0.0076). These findings suggested that the higher dose of dexamethasone may have a more pronounced effect on patients requiring MV.

DISCUSSION

This was the first RCT study that monitored and evaluated the impact of national guideline for the management of COVID-19 with high dose of dexamethasone in the first wave and low dose of dexamethasone in the second wave for the management of severe and critical ARDS caused by the COVID-19. Clinical trial is very important to compare these experimental data coming from clinical trials with the real use of medications in clinical practice [6]. The World Health Organization (WHO) reported "corticosteroids are lifesaving medicines recommend for patients with severe or critical COVID-19. They should be given along with standard care for COVID-19 which includes oxygen, MV, and other medications. On the other hands, the WHO should not be given to patients with non-severe [20, 21]. A RCT of Montalvan *et al*. concluded that the high dose of dexamethasone was associated with increased the mortality, intubation risk, and nosocomial infections [22]. A RCT was carried out by Wu *et al*. that concluded "dexamethasone 20 mg daily did not result in better clinical outcome improvement and was probably associated with higher 28-day mortality in patients on high-flow oxygen or non-invasive ventilation, compared with dexamethasone 6 mg daily"[23]. A RCT was carried out by Tomazini *et al*. that concluded in COVID-19 patients and moderate or severe ARDS using intravenous of dexamethasone plus standard care compared with standard care alone resulted in a statistically significant increase in the number of ventilator-free days (days alive and free of MV) over 28 days [24].

In addition, RCT has demonstrated that dexamethasone improves the outcomes in patients on oxygen or MV. These patients often need prolonged high-level ICU [5]. Al Kamarany *et al*. reported several risk factors that effected on dexamethasone-based therapeutics response and recovery outcomes were 67.3% of old age, 65.3% of chronic diseases where the most prevalent were diabetes mellitus along or diabetes mellitus associated with other chronic diseases that were 18.36% and 16.32%, respectively, followed by 12.24% of cardiac disorders and hypertension, 10.20% of respiratory disorders, 4.08% of cardiac disorders with respiratory disorder, 4.08% of renal failure, and 4.08% of co-infection [3]. Furthermore, in the previous study, COVID-19 persons with uncontrolled diabetes appear to be more likely to sustain lung damage, necessitating admission to the ICU, an extended stay in the hospital, and oxygen assistance throughout the duration of the illness [25]. On the other hand, corticosteroid therapy is associated with a sizable reduction in the duration of MV and hospital mortality. One of the major risk factors associated with corticosteroid therapy is associated with acquiring secondary infections [26]. Furthermore, other factors were reported that can be contributed in failure of dexamethasone effectiveness in Hodeidah area because it is endemic area for malaria and dengue, and previous study reported that co-infections with other infection like dengue are of high concern and this is the first reported case of COVID-19 and dengue co-infection [27]. In addition, pregnant women were presented as stroke and highlight the

complex context of diagnostic and therapeutic management in tropical settings such as Hodeidah, Yemen [27,28].

CONCLUSION

Based on RCT design, the study assessed the pharmacoepidemiology of COVID-19, namely dexamethasone effectiveness in high and low dose in treating COVID-19 patients hospitalized in Hodeidah, Yemen. Our finding found improvement of severe patients with high and low dose (no difference in outcomes). On the other hand, the impact of high dose of dexamethasone was better than low dose of dexamethasone in critical cases with MV (difference in outcomes).

CONFLICT OF INTEREST

Authors have declared that no competing interests exist.

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CONTRIBUTION OF AUTHORS

This work was carried out in collaboration among all authors. M.A Al Kamarany wrote, revised, and edited the final manuscript and was responsible for summarizing all epidemiological and clinical data; Abdullah H Maad contributed to revising the manuscript; Ali Ahmed Mohajab contributed in study design and revision of manuscript. Finally, I. Al-Masrafi contributed to the revision of manuscript. All authors read and approved the final manuscript.

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