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ORIGINAL RESEARCH

Side Effects and Adverse Events of Vaccines against COVID-19

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ABSTRACT: This study is to identify the side effects of vaccinations for Libyan individuals to protect from the Covid-19 virus, and it is to determine the actual COVID-19 vaccine with

less adverse events or complications. The present work was conducted on different medical centers in the east, west, south and central regions of Libya in the period from1/9/2020 to 1/9/2021. About 989 vaccinated individuals (537 males and 452 females) aged (20-70) years were selected according to their symptoms after taking the vaccine. A several doctors and nurses from the east, west and south and central regions of Libya were subjected to provide details about the vaccinated individuals. The questionnaire form includes questions about effectiveness and types of vaccine, vaccine's symptoms; the most resistant age group, the most age group had a high death rate, and the safest vaccines. The largest number of reported vaccinated cases was from western region (n =652), especially Tripoli (n= 466). Old individuals had more side effects than young people. Old men had more side effects than old women. No cases reported from Ghat city in southern Libya because of long distance or poor communication affected on and data transmission. The main side effects from vaccination included headache, pain, bleeding, fatigue, muscle pain, cough, and swelling. The descending order of vaccination according to side effects includes AstraZeneca (58%), Sputnik V (30%), Sinopharm (9%) and Pfizer (2%). This indicates that Pfizer vaccine is the safest vaccine than other vaccination. 574 (58%) cases were fully recovered from side effects, 33 (3 %) were died after taking the vaccination, while 9 (0.9%) cases are still under treatment.

KEYWORDS: Vaccinations, COVID-19, Side Effects, Adverse Events, Old Individuals.

INTRODUCTION

World Health Organization (WHO) lists only nine COVID-19 vaccines that have been deemed safe and effective for emergency use in national immunization programmers (Ujlain, 2022). However, the approvals are based on evidence from randomized controlled clinical trials whose samples may not necessarily be representative of the general population. Furthermore, only provisional analyzes were performed for licensing purposes, the data did not allow a determination of the duration of protection and certain populations, such as pregnant women, were excluded. Therefore, active surveillance of vaccines through observational studies on the incidence of adverse events, cases of COVID-19 and hospitalization among vaccinated individuals over a specified time period is needed.

To conduct an active safety surveillance study, the World Health Organization has released a sample protocol for mass event surveillance studies (WHO, 2021) .People are invaded by a corona virus, their body quickly expel or kill it by releasing chemicals produce the defensive protein molecules or the phagocytes that kill or destroy virus (Yoshikawa et al., 2020; Söderhäll, 1999; Sun et al., 2009; Raulet, 2004).

These burdens devise a smarter defense system to protect against corona (Gabrielli et al., 2016). One burden provides long-term security against infection and another one protects with care and meticulous to prevent attack tissues (Stein et al., 2020). This defense is called immune system against corona. Defense is "a rudimentary term that is equally associated with defeat and victory, while immunity exudes strength and confidence" (Yatim & Lakkis, 2015). Innate and adaptive immunity represent the creation of an advanced biological system (Sagan et al., 2020). Also, left innate immunity defense mechanisms are encoded in the germ line through evolutionary time and passed down from generation to generation with slight improvements (Parohan et al., 2020) including complement system, screen-like receptors (TLRs), and phagocytes. Phagocytosis is not only essential for the detection and elimination of corona virus , but is also key to maintain normal tissue homeostasis, and repair damaged tissues or

eliminate quietly from aging cells (Janeway and Medzhitov, 2002).

The congenital immune system consists of a series of nonspecific (physical and chemical) barriers, together with circulating and pre-positioned cellular and molecular elements to prevent and/or rapidly neutralize microbial infection at the site of its entry into the body (Castro, 2020) Congenital primitiveness may be damaged in certain health conditions. For example, the skin has an essential role in providing physical protection, but its burns or wounds may be the entry way of virus into the body (Houghton et al., 2020) . The respiratory system also provides physical protection, such as the mucous membrane and cilia in the lining of the airways, which impedes virus from sticking to cell surfaces and facilitate their expulsion by sneezing or coughing, but smoking and air pollution impair those capabilities (Caroll and Prodeus, 1998).

As for the acquired immune system, it is constantly evolving and adapting (acquired) to each time it is exposed to pathogens that may invade the body at intervals and under successive conditions. Traits of acquired immunity include: diversity, memory, mobility, flexibility, self-discrimination, redundancy, and specificity (Kam et al., 2019) . Diversity refers to the ability of the immune system to respond to corona virus or strains of corona , and the "immunological memory" (Vesely et al., 2011; Raulet, 2004). Self, non-self tissues and cells help preventing body damage. Redundancy refers to the ability of the immune system to create components with similar biological effects such as inflammatory cytokines "proteins produced by the body that act as messages to cells to stimulate immune reactions" (Blasco-Baque et al., 2017; Tregoning et al., 2020).

Moreover, viral vector vaccines trigger strong immune responses that can lead to long-term protection; (Yulianto, 2018) . However, they may also cause serious complications, such thrombosis (Monagle et al., 2021). Inactivated vaccines, on the other hand, is safe for immune compromised individuals (Lim et al., 2021) usually induce a much weaker immune response than vector-based viral vaccines (Iversen and Bavari, 2021). This study is aimed to know the side effects from taking vaccinations for Libyan people to protect from the COVID-19 virus, and it is to determine the definite corona virus vaccine providing less adverse events or negative symptoms.

MATERIALS AND METHODS

Questionnaire Study Design

The research was conducted on several health centers in the east, west, south and central region of Libya in the period between 1/9/2020 and 1/9/2021. About 989 vaccinated individuals (537 males and 452 females) aged from 20 to 70 years were selected according to their symptoms after taking the vaccine. A several doctors and nurses from the east, west and south and central regions of Libya were subjected to this survey study. The questionnaire form consisted of three parts include:

First Part included questions about effectiveness of acquired and natural immunity, effectiveness of vaccine, types of vaccines used.

Second Part included questions about vaccine symptoms; the most resistant age group to COVID-19 through natural immunity, the most age group had a high death rate.

Third Part included questions about types of vaccines, the safest vaccines, adverse effects of vaccines and the most used vaccine.

The participants including doctors, specialists supervising and nurses were firstly asked to fill out the questionnaire form to know the effects and symptoms from use the vaccine.

Then questionnaire form were collected, classified and subjected to statistics work.

RESULTS AND DISCUSSION

The study included data on approximately 989 patients diagnosed with COVID-19 (537 males (54%) and 452 females (46 %) from all regions of Libya. Of 989 cases, there were 982 cases (99.3%) from Libya and 7 cases (0.7%) from foreign countries (Figure 1, 2). All these cases had negative effects of vaccinations.

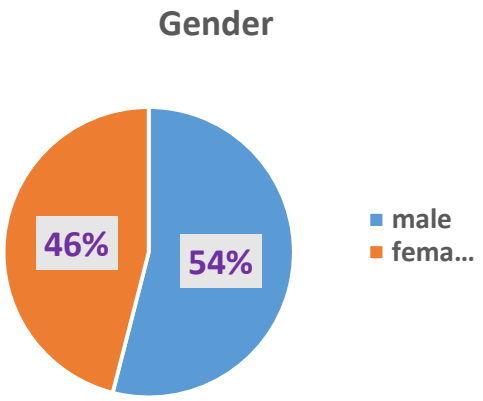

Figure: (1). Percentage of Vaccinated Males and Females Had Side effects.

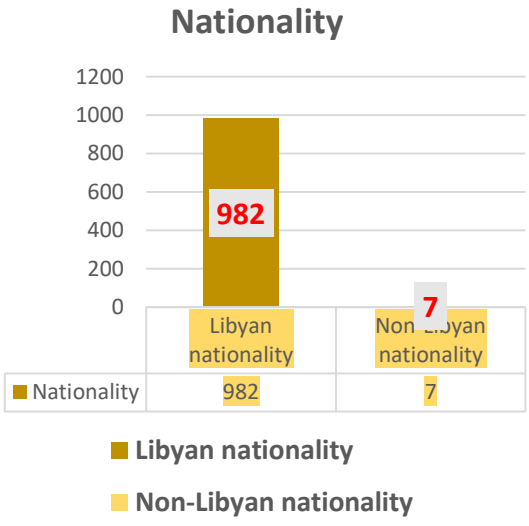

Figure: (2). Number of Reported Cases of Libyan and Foreign Vaccinated Individual with COVID-19 Vaccine.

The vaccinated individuals were aged from 20 to 70 years. The side effects and adverse events of vaccination increased with age. The patients aged 60 years old and above were more negatively affected by vaccination than other age groups. Old men had more side effect than old women. A prior study implied that people aged 60 years old and over were the most affected by the severity of the vaccine (Castro, 2020) .

Moreover, the monthly number of the reported vaccinated Libyan cases (Figure 3) was to show the side effects and adverse events of vaccination against COVID-19. Each report explains the data of the questionnaire form for each participant. The most reported vaccinated cases were received in June and included 316 reports, while the lowest reports were received in August, and included 31 reports. This perhaps public people started taking vaccinations for fear of contracting COVID-19, and then they may have negative attitude about vaccines which led to a decrease in reports of vaccinated cases.

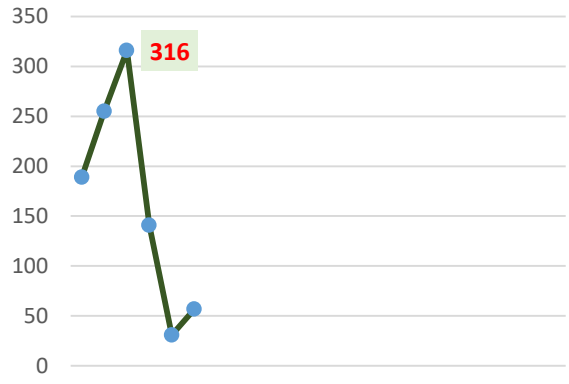

Figure: (3). Monthly Reports of Side Effects and Adverse Events of Vaccination.

Results exhibited the number of reported cases in regard to the effects of vaccinations according to Libyan regions. Each report explained the data of the questionnaire form for each participant. The study found that the

southern region provided 27 reports, while the central region sent 144 reports. Also, the western region submitted 652 reports and the eastern region sent 166 reports (Figure 4) .This indicates that the western region is considered more responsive and interactive in sending reports about COVID-19 vaccines. Also, the extend of the COVID-19 was the highest in western Libya because of the large population.

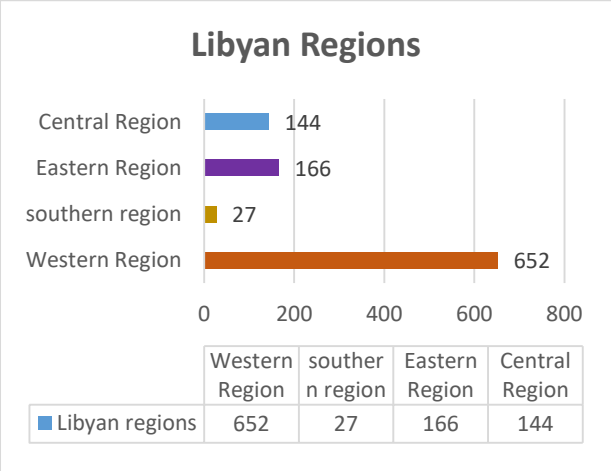

Figure: (4): Report's Notifications According to Libyan Region.

One is finding in this study that the largest number of reported vaccinated cases in Libyan cities was 466 cases from Tripoli, then 96 cases from Misurata. Whereas the lowest number of reported cases received from the city of Jfara was 1 without and no reports from Ghat city in southern Libya (Figure 5).

This may be due to the fact that the southern region is far from the areas infected with COVID-19, or because of long distance and poor communication affected data transmission.

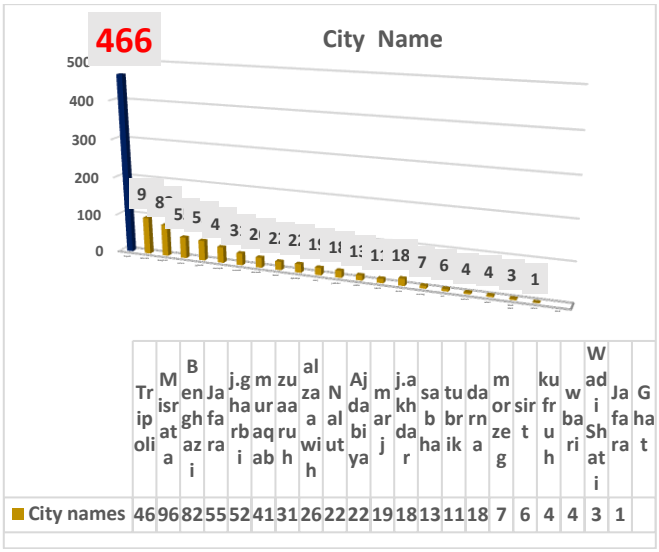

Figure (5) : Number of Reported Vaccinated Cases in Libyan Cities.

The present work provided that the most symptoms and side effects were from AstraZeneca vaccine (58%), while the Pfizer vaccine gave the least symptoms and side effects (2%). Also, the percentage of side effects and adverse events of Sputnik V vaccine was 30%, while the percentage of side effects and adverse events of the Sinopharm vaccine was 9%.

This indicates that Pfizer vaccine has less negative effect than other vaccines. The results showed that vaccinations caused many side effects including a headache, pain, bleeding, fatigue, muscle pain, cough, and swelling etc. (Figure 6). Headache and fatigue were the most common side effects that vaccinated individuals suffered from.

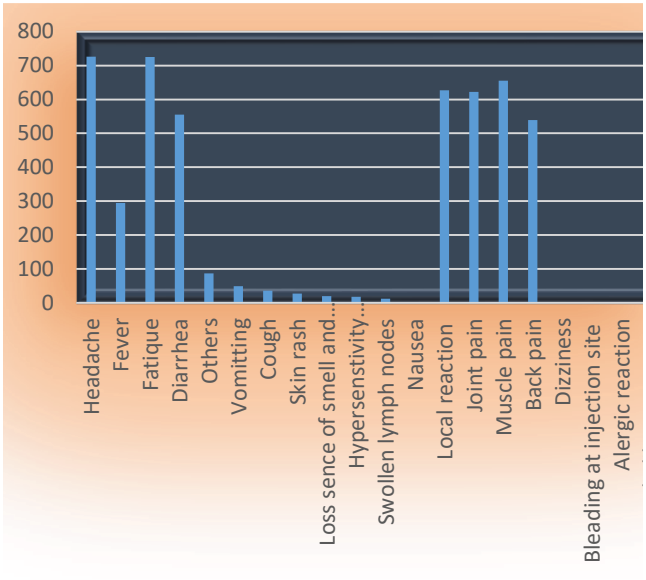

Figure (6) : Symptoms after Taking the Vaccine.

Among 989 vaccinated cases against COVID-19, about 955 (96.5%) cases had mild side effects, while 34 (3.4%) cases had serious symptoms from vaccinations (Figure 7).

The symptoms and side effects were continued after days from taking the vaccines (Figure 8). A previous study indicated that several negative symptoms may appear after taking the vaccines, (Kam et al., 2019).

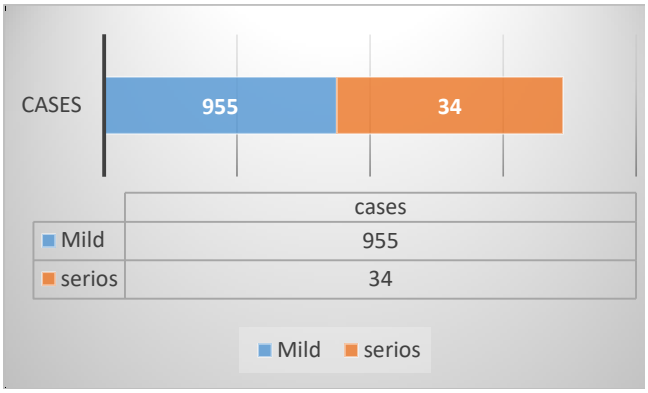

Figure (7): The Number of Mild and Serious Symptoms of Vaccinated Cases.

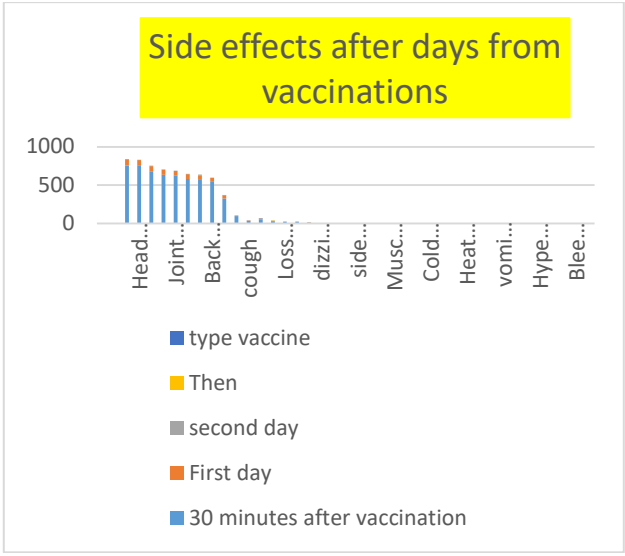

Figure (8): Percentage of Side Effects after Days from COVID-19 Vaccinations.

One of important finding in this study that AstraZeneca vaccine considers as the most vaccine caused negative serious side effect with a percentage of 67% followed by Sputnik vaccine (18%) and Sinovac vaccines (15%) .

In comparison, no serious side effect had been reported in individuals took Pfizer vaccine (Figure 9).

This is because Chinese vaccine (Pfizer) contains a dead virus, so the symptoms are mild with slightly rise in a temperature and do not exceed the feeling of pain at the place of the needle (Dintrans et al., 2021).

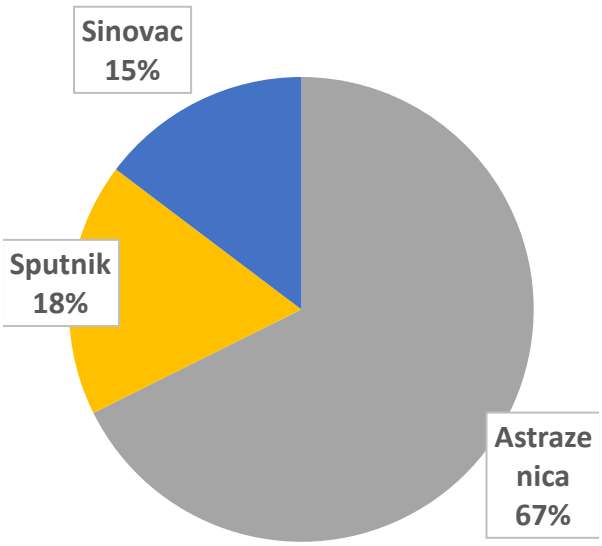

Figure (9) : Percentage % per Vaccine for Serious Vaccinated Cases.

Among 989 cases took COVID-19 vaccination, there were 574 (58%) cases were fully recovered from side effects, 33 were died after taking the vaccination , while 9 cases are still under treatment (Figure 10). A previous work by Yoshikawa et al., 2020 documented that some cases taken the vaccination were died.

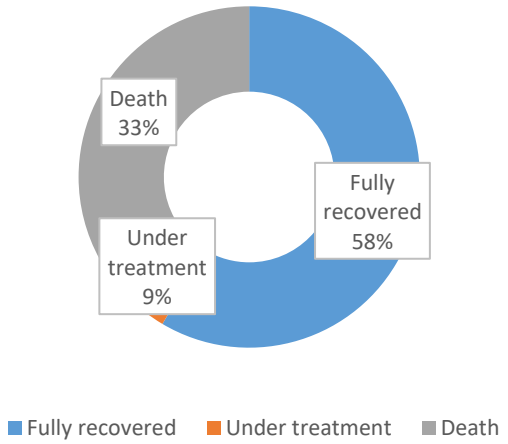

Figure (10) : Percentage of Fully Recovered, Under-Treatment and Died Cases from Vaccination

CONCLUSION

The side effects of vaccinations arranged from mild to severe. The severity of side effects varies according to ages, gender and vaccine's type. Old males had more side effects than old females. The descending order of vaccinations depending on side effects includes AstraZeneca (58%), Sputnik V (30%), Sinopharm (9%) and Pfizer (2%). This indicates that Pfizer vaccine provides lesser side effects than other vaccines. Most vaccinated cases were fully recovered from side effects. However, some vaccines are fatal.

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الملخص

تهدف هذه الدراسة إلى تحديد الآثار الجانبية للتطعيمات الوقائية ضد فيروس كوفيد-19 لدى الليبيين، وتحديد اللقاح الأكثر فعالية من حيث الآثار الجانبية والمضاعفات. أُجريت الدراسة في مراكز طبية مختلفة في شرق ليبيا وغربها وجنوبها ووسطها خلال الفترة من 1 سبتمبر 2020 إلى 1 سبتمبر 2021. تم اختيار 989 شخصًا مُطعمًا (537 ذكرًا و452 أنثى) تتراوح أعمارهم بين 20 و70 عامًا بناءً على الأعراض التي ظهرت عليهم بعد التطعيم. استُطلعت آراء عدد من الأطباء والممرضين من مختلف أنحاء ليبيا لجمع معلومات تفصيلية عن هؤلاء الأشخاص. تضمن الاستبيان أسئلة حول فعالية اللقاح وأنواعه، وأعراضه، والفئة العمرية الأكثر مقاومة، والفئة العمرية ذات أعلى معدل وفيات، واللقاحات الأكثر أمانًا. سُجل أكبر عدد من حالات التطعيم في المنطقة الغربية (652 حالة)، وخاصة في طرابلس (466 حالة). وقد لوحظت آثار جانبية أكثر لدى كبار السن مقارنةً بالشباب. عانى الرجال المسنون من آثار جانبية أكثر من النساء المسنات. لم تُسجّل أي حالات في مدينة غات جنوب ليبيا بسبب بُعد المسافة أو ضعف الاتصالات الذي أثّر على نقل البيانات. شملت الآثار الجانبية الرئيسية للتطعيم الصداع، والألم، والنزيف، والإرهاق، وآلام العضلات، والسعال، والتورم. وبحسب ترتيب التطعيمات من حيث الآثار الجانبية، كانت النتائج كالتالي: أسترازينيكا (58%)، سبوتنيك V (30%))، سينوفارم (9%)، وفايزر (2%). يشير هذا إلى أن لقاح فايزر هو الأكثر أمانًا من غيره. تعافى 574 شخصًا (58%) تمامًا من الآثار الجانبية، وتوفي 33 شخصًا (3%) بعد التطعيم، بينما لا يزال 9 أشخاص (0.9%) يتلقون العلاج.

الكلمات المفتاحية: التطعيمات، كوفيد-19، الآثار الجانبية، الأحداث الضائرة، كبار السن.