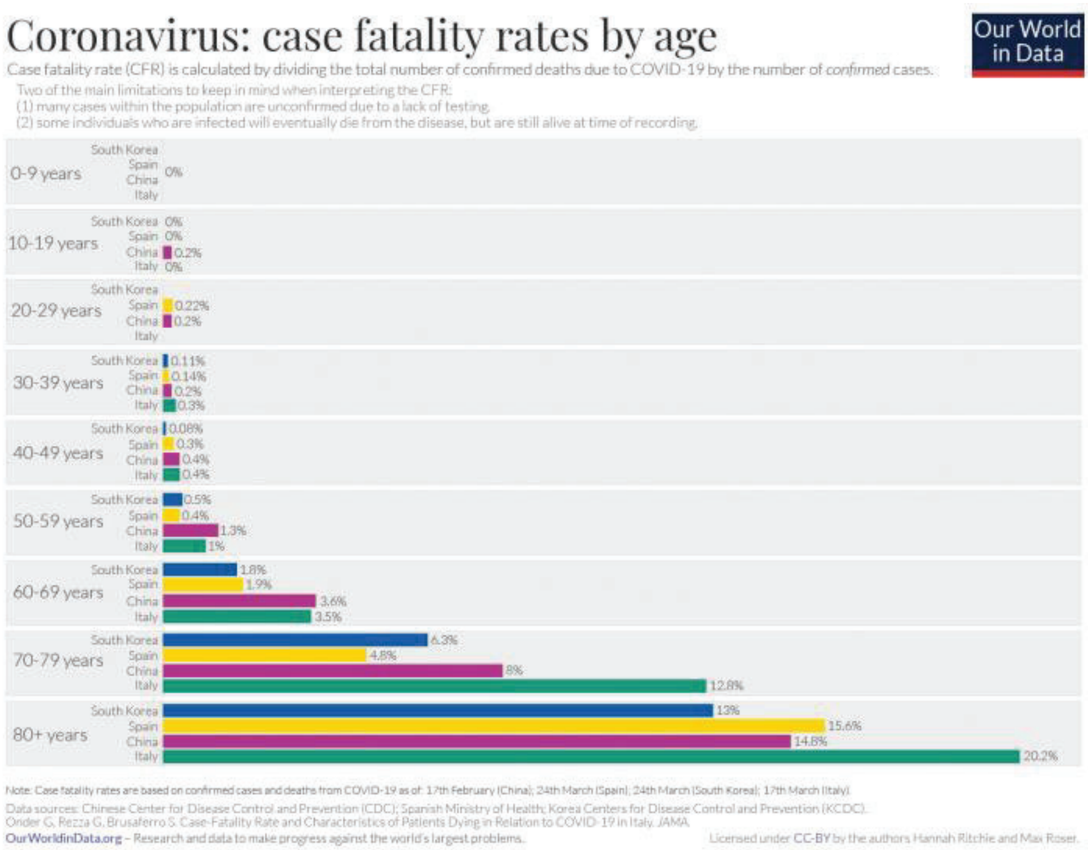
חיסון קורונה, תופעת ADE

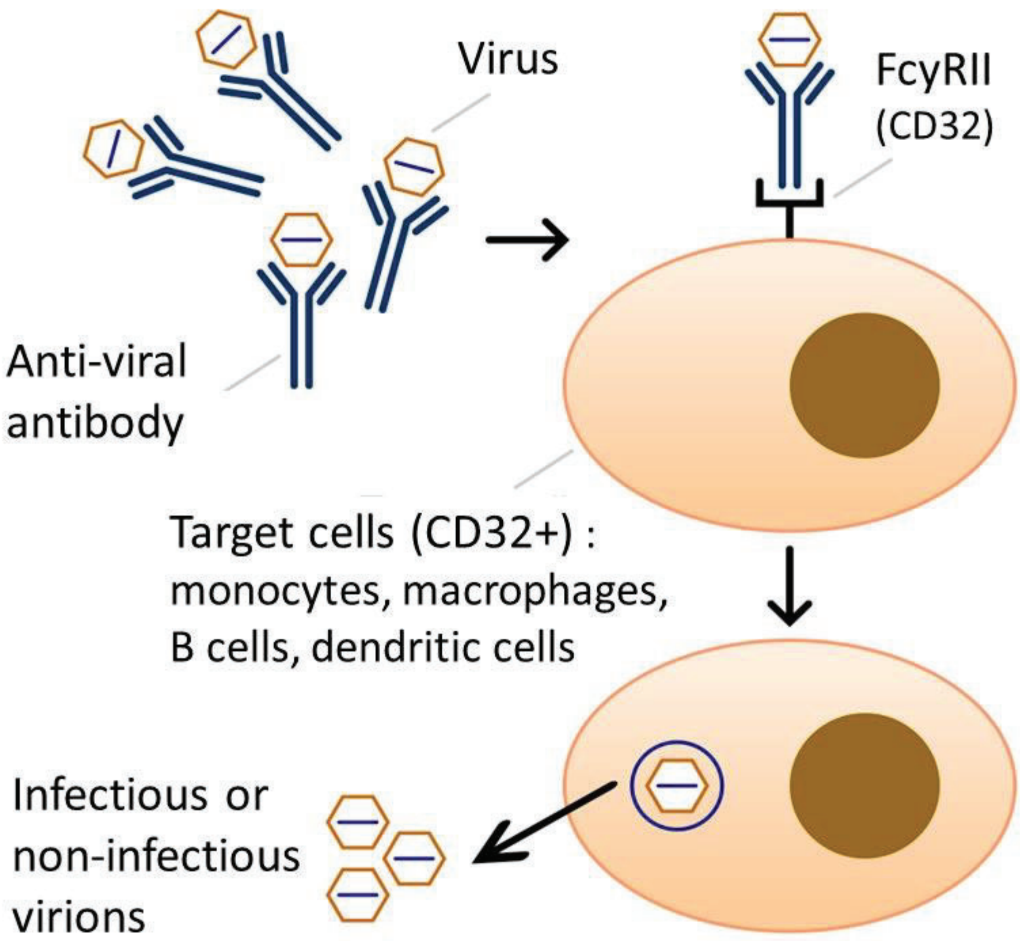
מחלת נגיף קורונה 2019 (ידועה גם בשם מחלת הקורונה; באנגלית: Coronavirus disease 2019 ובקיצור COVID-19, קרי: קוֹבִיד־19) היא מחלה זיהומית, הפוגעת בבני אדם ונגרמת על ידי הנגיף SARS-CoV-2, מתת-משפחת נגיפי קורונה. המחלה התפרצה לראשונה בווהאן, בירת מחוז חוביי שבסין בשנת 2019. דהיום מספר הנפטרים בישראל מהמחלה מתקרב בעת כתיבת מכתב זה כמעט ל3000. ברור מאליו שחיסון נגד נגיף הקורונה הוא מטרה חשובה ונעלה. השאלה המרכזית הנשאלת כעת לאחר אישור החיסונים של פייזר ומודרנה האם זה הפתרון המיוחל? או שאנחנו עלולים להיות במצב בו החיסון עצמו יגרום לנזק גבוה יותר, מאשר הנגיף עצמו .

כלל ידוע ברפואה הוא דבר ראשון לא לגרום נזק למטופל. כלל שני אשר ידוע הוא העניין של תועלת מול סיכון . אם ניקח אחוזי תמותה לפי גיל ומחלות רקע אזי הקבוצה היחידה בה חיסון כלשהוא יכול לשנות לטובה את המצב זה אוכלוסיית הקשישים ואלו אשר עם מחלות רקע מרובות. לכל הקבוצות האחרות באוכלוסייה אין שום משמעות קלינית לחיסון עצמו .כי אצלם התמותה והסיבוכים מהמחלה מאד נמוכים . לדוגמא: אנחנו לא נותנים חיסון לשלבקת חוגרת לאנשים צעירים כי אין טעם בכך . אנחנו כן ניתן למי שיש לו מחלות רקע או גיל .



הטענה של אלו אשר בעד נתינת חיסון לאוכלוסייה הכללית היא שמתן חיסון לכל האוכלוסייה יוריד מספר נדבקים ואז בדרך הזאת נגיע לחיסון עדר ומשם הגנה על הקשישים . לכאורה רעיון מעולה ואידאלי, אבל ההיסטוריה רצופה ברעיונות מעולים ונעלים אשר הובילו בסופו של דבר לאסונות קולוסאליים .

תגובת ADE (Antibody-dependent enhancement (ADE). זוהי תופעה מוכרת לכל מי שעוסק בפיתוח של חיסונים במיוחד בפיתוח חיסונים לנגיפי הקורונה השונים .



מדובר בתופעה שבה הגוף מייצר נוגדן נגד הנגיף , הנגיף בתגובה מתחבר לנוגדן , עושה איתו קומלפקס ומשם הוא מדביק את התאים וגורם למעשה למחלה חמורה יותר . הסיבה המרכזית לכישלון של חיסונים לנגיפי הקורונה למיניהם בעבר קשורה חד משמעית לתופעה הזאת.

ב2003 כאשר נגיף הסארס פרץ לעולם , החל מרוץ ליצירה של חיסון אפקטיבי , ב2005 הקבוצה מאוקספורד הראתה חיסון אפקטיבי בקופים . החיסון דווח כבטוח , הנוגדנים היו ברמה גבוהה והקופים הדגימו גם מקדם בטיחות גבוה והכל נראה מבטיח ויפה . "יש פתרון לסארס ", אלא מה במחקרים יותר מאוחרים כאשר אותם קופים מחוסנים נחשפו לוירוס הפראי שקצת שונה מוירוס המעבדה אקפט ADE, נכנס לפעולה והקופים המחוסנים התפגרו אחד אחרי השני .כמובן שהחיסון לסארס נעצר ולא עבר לשלב הקליני בבני אדם . מה שהתברר היה שחיסון עצמו לאיזור הספייק גרם לקופים המחוסנים להיות הרבה יותר פגיעים מהקופים הלא מחוסנים כאשר וריאנט קצת שונה של הנגיף בא איתם במגע. בהמשך נעשו מחקרים רבים על מודלים של חיות שונות שהדגימו פעם אחר פעם את התופעה הזאת .

הטבלה הבאה מסכמת את כל הניסויים שנעשו בעבר והמודלים השונים של החיסונים בקורונות למיניהם ומה קרה לחיות המחוסנות. וכיצד תופעת ADE נראתה בשטח.

Virus	Animal	Vaccine type	Vaccination	Protective	Immuno-pathology	Ref.

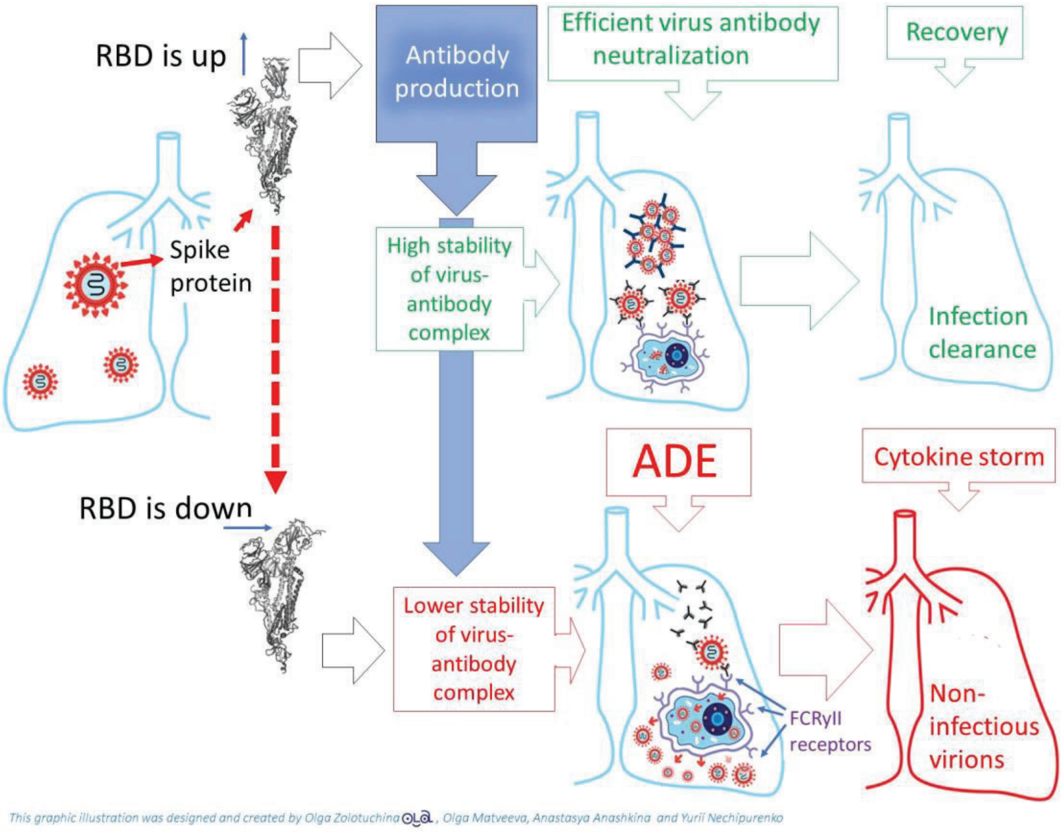
MERS-CoV	Mice	Whole Inactivated Virus	No Adjuvant	Yes	Yes	[99]
			Alum	Yes	Yes	
			MF59	Yes	Yes	
		Adenovirus Vector	S1	Yes	Pulmonary perivascular hemorrhage	[100]
			S1 + CD40L	Yes	No	
SARS-CoV	Mice	Whole Inactivated Virus	No Adjuvant	Yes	Th2-type immunopathology with prominent eosinophil lung infiltration	[92][101][102]
			Alum	Yes	Th2-type immunopathology with prominent eosinophil lung infiltration	[101][103][92]
			TLR agonist	Yes	Mild	[101]
			delta inulin adjuvant [104]	Yes	No	[102]
			No Adjuvant – Aged Mice	Partial	Yes	[103]
			Alum – Aged Mice			
		DNA vaccines	These vaccines are described in a separate review			[96]
		Venezuelan Equine	S protein			

		Encephalitis Vector				
			Young mice	Yes	No	[105]
			Aged mice	Partial		
			N protein			
			Young mice	No	Yes	[105]
			Aged mice			
			S + N protein			
			Young mice	Yes	Mild	[105]
			Old mice	No		
		Recombinant Vaccinia Virus Vector	S protein	Yes	No	[69]
			N Protein	No	Yes	
			S + N Protein	Yes	Yes	
			E, M	No	No	
		Variable Virus vectors	More vaccines are described in a separate review			[96]
		Virus Like Particle	Alum	Yes	No	[106]
		Subunit	S protein			
			No Adjuvant	Yes	Yes	[92][102]
			Alum			

			Delta inulin adjuvant	Yes	No	[102]
			TLR agonist	Yes	No	[107]
			S1 RBD			
			hFCA Adjuvant	Yes	No	[108]
			Proteins	More vaccines are described in a separate review		[96]
	Ferret	Whole Inactivated Virus	No adjuvant	Infection delay, multiple organ damage	Not clear	[109]
			Alum			
		Adenovirus Vector	S + N protein			
			Intra-nasal	Infection delay, multiple organ damage	Not clear	[109]
			Intra-muscular			
		Modified Vaccinia Virus Ankara Vector	S protein	Partial	Liver damage	[97]
	Hamster	Live Attenuated Virus		Yes	Mild	[110]
		Whole Inactivated Virus	No Adjuvant	Yes	Mild	[111]
			AS01	Yes	Mild	
		Subunit	S protein trimer			

			No Adjuvant	Yes	No	[85]
			Alum	Yes	No	
	Non Human Primate	Modified Vaccinia Virus Ankara Vector	S protein	Yes	Acute lung injury	[36]
		Whole Inactivated Virus		No	No	[95]
		B-cell peptide-epitopes	Three peptides from Spike protein (S471-503, S604-625, and S1164-1191)	Yes	No	[33]
			One peptide from Spike protein (S597-603)	No	Yes	

התמונה הבאה ממחישה את הסכנה של התופעה גם בקוביד 19



לסיכום : במצב הנוכחי כאשר החיסונים המדוברים לא עברו את כל התהליך הבטיחותי כנדרש . וקבלת האישור מה FDA למעשה היא מותנית ורק זמנית כחיסון חירום בלבד . נשאלת השאלה של תועלת מול סיכון . ברור מאליו שכן יש צורך במציאת חיסון כפתרון . אבל יש כאן סכנה די רבה . נניח נחסן את כלל האוכלוסייה ,ואז בשנה הבאה הנגיף, כמו שנגיפי קורונה נוהגים לעשות יעשה מוטציה . לא רק שהחיסון יוגדר כלא יעיל. אלא אנחנו עלולים לסכן אוכלוסיות שכעת לא במצב של סכנה , קרי ילדים, צעירים ואחרים , להיות במצב בו החיסון יגרום להם להיות פגיעים הרבה יותר לאחר קבלת החיסון . מכיוון **שהחיסון בקבוצות הללו לא יוריד תמותה כי אין למעשה תמותה בקבוצות הגיל הללו** . יכול להיווצר **מצב פרדוקסלי** שבו צעירים אשר יקבלו את החיסון , כאשר יפגשו וירוס פראי , בדיעבד ממצב של מסוכנות אפסית , נגיע למצב של מסוכנות גבוהה. **האם מישהוא יקח אחריות על כך** אם זה יקרה? **האם נסכן מיליוני צעירים וצעירות בישראל במשהוא שעלול להביא לתוצאה הרבה יותר חמורה מאשר אם נניח הם יחלו בקורונה?.**

לגבי קבוצות גיל מאוחרות יותר קרי קשישים, ואנשים עם מחלות רקע , בגלל שבהם כן יש מצב לסכנה מהנגיף אזי בשיקול רווח מול סיכון כן יש ,כאן ורק כאן תועלת ממשית .

יש לציין כי לגבי אוכלוסיית הקשישים –לא ברור אם הנסיינים מהדאטה במחקר של פייזר או מודרנה כמה מהם הגיבו או לא הגיבו לחיסון . דבר שמצריך ביקורת נוספת או הבהרה ברורה לגבי הנושא .

דבר נוסף שחייב בירור הוא שהחיסונים המדוברים הם טכנולוגיה חדשנית שמעולם לא נוסתה בבני אדם , לכן יש צורך בזמן נוסף לוודא שהיא באמת בטוחה כמו שהמפתחים טוענים שהיא.

כרופאים המטרה שלנו קודם להציל חיים ולמנוע מוות מיותר , לפי דעתי כל זמן שהנושא של ADE לא נחקר כיאות, וזה דורש זמן ומחקרים נוספים עלידי קבוצות מחקר שלא קשורות לחברות התרופות . אין צורך לסכן אוכלוסייה שלמה שברור מאליו לא נמצאת בסיכון ממשי לנגיף .

הכותב הינו רופא מיון בכיר עם מומחיות ברפואה פנימית , כעת עובד כרופא מיון בכיר בבית חולים לניאדו. רקע מחקרי של שמונה שנים בתחום הוירולוגיה . באוניברסיטת וושינגטון וסטנפורד כפוסט דוקטורט ו Senior Fellow .

ד"ר ציוני רפאל

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