

سلام عرض می کنم خدمت همکاران گرامی

در این فایل به صورت مختصر نکات مهم پروتوکل جمع آوری داده های بیماران رو تقدیم می کنم:

هدف مطالعه چیه؟

مقایسه عوارض و مرگ و میر 30 روزه بیمارانی که قبل از عمل جراحی مبتلا به کووید 19 بوده اند با کسانی که مبتلا نبوده اند!

1- بازه های زمانی که می تونیم اطلاعات بیماران رو جمع کنیم 7 روزه و فقط در بازه های زیر هست

یعنی هر تیم سه نفره فقط برای یکی از این هفت روز داده ها رو جمع می کنه

Period 1: 00:00 on 5 October 2020 to 23:59 on 11 October 2020

Period 2: 00:00 on 12 October 2020 to 23:59 on 18 October 2020

Period 3: 00:00 on 19 October 2020 to 23:59 on 25 October 2020

Period 4: 00:00 on 26 October 2020 to 23:59 on 1 November 2020

2- یک سری موارد هستند که جزو پروسجرهای مینور محسوب می شن و نباید در مطالعه وارد بشن که به شرح زیر هستند:

Specialty	Excluded procedures
Abdominal surgery	Ascitic drain (drainage of peritoneal cavity)
	Endoscopic ultrasound
	Laparoscopic ultrasound
Breast surgery	Breast biopsy
Cardiac surgery	Insertion of cardiac pacemaker
	PCI: percutaneous coronary intervention
	Transluminal balloon angioplasty of coronary artery
Colorectal surgery	Colonoscopy (diagnostic or therapeutic)
	Flexible sigmoidoscopy (diagnostic or therapeutic)
	Proctoscopy (diagnostic or therapeutic)
Dental procedures	Implantation of tooth
	Insertion of dental prosthesis
	Orthodontic operations
	Restoration of tooth
	Simple extraction of tooth
Gynaecology	Cervical biopsy
	Colposcopy (diagnostic or therapeutic)
Obstetrics	Any vaginal delivery (normal delivery, breech delivery, forceps delivery, vacuum delivery)
	Repair of obstetric laceration
Ophthalmology	Removal of foreign body from cornea
Orthopaedics	Bone biopsy
	Injection in to joint
	Muscle biopsy
Other	Insertion of central venous catheter/ line (CVC)
	Lumbar (spinal) puncture
	Percutaneous tracheostomy
	Skin biopsy (including shave biopsy of skin)

	Therapeutic epidural injection
Otolaryngology	Nasendoscopy (diagnostic or therapeutic)
	Packing of cavity of nose
Thoracic surgery	Bronchoscopy (diagnostic or therapeutic)
	Chest drain
Upper gastrointestinal surgery	ERCP: endoscopic retrograde cholangiopancreatography (diagnostic or therapeutic)
	Liver biopsy
	OGD: Oesophago-gastro-duodenoscopy (diagnostic or therapeutic)
Vascular surgery	Transluminal (endovascular) procedures on arteries (diagnostic or therapeutic)
	Transluminal (endovascular) procedures on veins (diagnostic or therapeutic)

3- چه بیمارانی کرونایی محسوب می‌شن؟ (یکی از چهار مورد زیر حتی به تنهایی قابل قبوله)

- Positive RT-PCR swab.
- Positive antibody test.
- Positive CT thorax.
- Clinical diagnosis of SARS-CoV-2 (no negative swab results). The diagnosis should be made contemporaneously (i.e. at the time that the patient has the symptoms) by a healthcare provider. A chest x-ray may be used as part of a clinical diagnosis.

4- چه بیمارانی در گروه کیس مطالعه قرار می‌گیرند؟

بیمارانی که هر زمانی قبل از جراحی (از شروع پاندمی تا شروع جراحی) به کرونا مبتلا شده اند چه با علامت و چه بی علامت

(اگر بیماری در حال حاضر مبتلا نیست و قبلاً مبتلا بوده باید زمان دقیق ابتلا مشخص بشه)

5- چه بیمارانی در گروه کنترل یا مقایسه قرار می‌گیرن؟

الف) بیمارانی که نه قبل از عمل سابقه کرونا داشتند و نه در طی مدت 30 روز فالوآپ به کرونا مبتلا شدند

ب) بیمارانی که بعد از عمل جراحی و در طی مدت 30 روز فالوآپ به کرونا مبتلا شدند

6- حالا قراره که ما چه پیامدهایی رو در بیماران در نظر بگیریم؟ چه مواردی رو باید بررسی کنیم؟ (به طور کلی

دو دسته عوارض ریوی و سایر عوارض مد نظر هست که شرایط و کرایتریای هر کدام رو در ادامه می‌نویسم): این عوارض

اگر در طی فالوآپ 30 روزه بیماران وجود داشتند باید ثبت بشن چه بیمار ترخیص شده باشه و چه بیمار بستری باشه

هنوز!

اولی:

Postoperative pulmonary complications.

- 1- postoperative pneumonia,
- 2- acute respiratory distress syndrome (ARDS)
- 3- unexpected ventilation.

دومی:

Clavien-Dindo Classification System

Adverse post-operative events may be classified as:

- Failure of treatment – This occurs when the original surgery fails to achieve its intended benefits; for example, persistent pain following laparoscopic cholecystectomy or tumour recurrence following cancer surgery.
- Sequelae: The recognized consequences of a given procedure; for example, gut malabsorption following a large small bowel resection or immune deficiency following splenectomy.
- Complication: Any deviation from the normal post-operative course that has an adverse effect on the patient and is not either a treatment failure or sequel.

نکته: عوارض حین عمل نیاز به ثبت کردن ندارند مگر مرگ حین عمل که باید ثبت بشه!

این هم روش گرید بندی عوارض در بیماران

Grade	Definition (examples listed in italics)
I	Any deviation from the normal postoperative course without the need for pharmacological (other than “allowed therapeutic regimens”), surgical, endoscopic or radiological intervention. Allowed therapeutic regimens are: selected drugs (antiemetics, antipyretics, analgesics, diuretics and electrolyte replacement), physiotherapy and wound infections opened at the bedside but not treated with antibiotics. <i>Examples: Ileus (deviation from the norm); hypokalaemia treated with K; nausea treated with cyclizine; acute kidney injury treated with intravenous fluids.</i>
II	Requiring pharmacological treatment with drugs beyond those allowed for grade I complications; including blood transfusions; total parenteral nutrition. <i>Examples: Surgical site infection treated with antibiotics; myocardial infarction treated medically; deep venous thrombosis treated with enoxaparin; pneumonia or urinary tract infection treated with antibiotics; blood transfusion for anaemia.</i>
III	Requiring surgical, endoscopic or radiological intervention <i>Examples: Therapeutic endoscopic therapy (do not include diagnostic procedures); interventional radiology procedures; return to theatre for any reason</i>
IV	Life-threatening complications requiring critical care management; brain haemorrhage; or ischemic stroke (excluding TIA). <i>Examples: Pneumonia with ventilator support, renal failure with filtration; SAH; stroke</i>
V	Death of a patient

این هم مواردی هست که باید حین پذیرش بیماران چه اورژانسی و چه الکتیو رعایت بشه:

- “Emergency Admissions: all patients should be tested on admission.”
- “Elective Admissions: patients should isolate for 14 days prior to admission. This should be supplemented with a pre-admission test [if feasible].”
- “There should be a physical separation of COVID-19 positive and COVID-19 negative patients”.

این هم فرمی هست که بر اساس اون باید اطلاعات بیماران جمع آوری بشه

Baseline	
Age	<52 weeks, 1-4 years, 5-9 years, 10-17 years, 18-29 years, 30-39 years, 40-49 years, 50-59 years, 60-69 years, 70-79 years, 80-89 years, ≥90 years
Sex	>Female >Male >Ambiguous
ASA	>Grade I >Grade II >Grade III >Grade IV >Grade V
Revised Cardiac Risk Index	>History of ischemic heart disease >History of congestive heart failure >History of cerebrovascular disease >Pre-operative treatment with insulin >Pre-operative creatinine >2 mg/dL / 176.8 μmol/L
Respiratory comorbidities	>Current smoker or smoked in last 6 weeks >Ex-smoker (stopped ≥6 weeks ago) >Asthma >COPD >Other respiratory comorbidity
SARS-CoV-2 status	

Hot/cold unit	<p>Operating theatre</p> <p>>Cold: dedicated theatre for non-SARS-CoV-2 elective surgery patients, segregated from COVID-19 patients</p> <p>>Hot: area shared by elective surgery patients and COVID-19 patients</p> <p>Intensive care unit</p> <p>>Cold: dedicated ICU for non-SARS-CoV-2 elective surgery patients, segregated from COVID-19 patients</p> <p>>Hot: area shared by elective surgery patients and COVID-19 patients</p> <p>>Not applicable</p> <p>Postoperative ward</p> <p>>Cold: dedicated ward for non-SARS-CoV-2 elective surgery patients, segregated from COVID-19 patients</p> <p>>Hot: area shared by elective surgery patients and COVID-19 patients</p>
Was the patient asked to self-isolate	<p>>No</p> <p>>Before hospital admission only</p> <p>>After discharge from hospital only</p> <p>>Both before hospital admission and after discharge from hospital</p> <p><i>If yes, duration of preoperative and postoperative isolation in days</i></p>
<p>Were any of the following used to screen the patient for SARS-CoV-2 in the 7 days before surgery</p> <p><i>(tick all that apply)</i></p>	<p>>CT thorax scan</p> <p>>Chest x-ray</p> <p>>Swab >> how many negative swabs / positive swabs & timing of the last swab</p> <p>>Antibody test</p> <p>>Clinical screening (history, examination)</p>
SARS-CoV-2 diagnosis	<p>>None</p> <p>>Preoperative (at any time)</p> <p>>Postoperative (within 30 days after surgery)</p>

<p><i>If SARS-CoV-2 +ve</i></p> <p>How was the diagnosis made (tick all that apply)</p>	<p>>Positive swab</p> <p>>CT thorax</p> <p>>IgG antibody positive</p> <p>>IgM antibody positive</p> <p>>Clinical diagnosis</p>
<p><i>If preoperative infection</i></p> <p>How long before surgery was the diagnosis</p>	<p>>Day of surgery</p> <p>>1-7 days before surgery</p> <p>>8-14 days before surgery</p> <p>>15-28 days before surgery</p> <p>>5-6 weeks before surgery</p> <p>>7-8 weeks before surgery</p> <p>>3-4 months before surgery</p> <p>>5-6 months before surgery</p> <p>>6+ months before surgery</p>
<p><i>If preoperative infection</i></p> <p>Was the SARS-CoV-2 infection symptomatic*</p>	<p>>Yes- but all symptoms had resolved before the day of surgery</p> <p>>Yes- and some symptoms were ongoing on the day of surgery</p> <p>>No- the patient did not have symptoms</p> <p>*this includes both respiratory and non-respiratory symptoms</p>
<p><i>If symptomatic infection</i></p> <p>What symptoms did the patient have (tick all that apply)</p>	<p>>Respiratory symptoms (e.g. cough, shortness of breath)</p> <p>>Non-respiratory symptoms (e.g. fever, diarrhoea, fatigue)</p>
<p><i>If symptomatic infection</i></p> <p>Did the patient require hospital treatment for SARS-CoV-2</p>	<p>>No</p> <p>>Yes- did not require non-invasive or mechanical ventilation</p> <p>>Yes- required non-invasive or mechanical ventilation</p>

<i>If postoperative infection</i> Was dexamethasone administered in the 10 days following infection	>No >Yes >> enter dose, duration
Intraoperative	
Urgency	>Elective >Emergency
Day-case surgery	>Performed as day-case (no overnight admission) >Performed with overnight admission
Procedure	Dropdown menu of procedures
Anaesthesia <i>Tick all that apply</i>	>Local >Nerve block >Spinal >Epidural >General
Indication	>Benign >Malignancy >> curative or palliative procedure >Trauma >Obstetric >Complication of COVID-19 >> free text field to describe
<i>If abdominal surgery</i> Operative approach	>Planned and performed as open >Planned and performed as laparoscopic (includes laparoscopic assisted cases) >Planned and performed as robotic >Laparoscopic converted to open >Robotic converted to open >Hybrid (e.g. laparoscopic abdomen, open chest)

How was the majority of the cost of surgery supported?	<ul style="list-style-type: none"> > Public insurance (funded by government) > Private insurance (insurance paid for by the patient) > Corporate insurance (funded by patient's employer) > External funds or grants awarded by charities/NGOs > Out of pocket payments (patient paid the hospital directly) > Other (free text)
Outcomes	
Mortality	<ul style="list-style-type: none"> >Alive at 30 days >Died in-hospital, within 30 days of surgery >Died after discharge, within 30 days of surgery
Complications	<ul style="list-style-type: none"> >None >Pneumonia >Acute respiratory distress syndrome >Unexpected ventilation >Pulmonary embolism >Deep vein thrombosis
Clavien-Dindo	<ul style="list-style-type: none"> >Grade I >Grade II >Grade IIIa/b >Grade IVa/b >Grade V

ارادتمند همه عزیزان

اگر سوال یا مشکلی بود از طریق تلفن و ایمیل پاسخ گو هستم

دکتر محمد حسین خسروی

Iran's Covid-Surg-Week study National leader

Kind Regards,

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