

## Achieving safe surgery after COVID-19 vaccination

COVID-19 has changed surgery worldwide.<sup>1</sup> As surgical outcomes for patients with COVID-19 are significantly poorer than those without,<sup>2</sup> one of the most important preventative measures for surgical safety has been vaccination, which dramatically reduces transmission and disease severity. Predicated largely on favourable phase II/III clinical trials, several vaccines have been rolled out internationally with phase IV outcomes meeting expectations.<sup>3</sup> Despite evidence supporting the safety and efficacy, it has been challenging to develop evidence-based guidelines for safely providing vaccination and surgical care worldwide. Consideration of risks is necessary at the individual patient level. This perspective piece aimed to explore factors relating to available COVID-19 and provide recommendations for undertaking surgery in those who have been recently vaccinated. For each clinical statement made, a level of evidence, according to the evidence hierarchy outlined by Merlin *et al.*,<sup>4</sup> is provided. The levels of evidence provided represent the body of literature retrieved in a report undertaken by the Royal Australasian College of Surgeons that incorporated a formal search strategy.<sup>5</sup> This article represents a major collaborative effort, and all listed authors contributed to the manuscript's conception, analysis and interpretation of data, revised the article critically for important intellectual content, and provided final approval of the version to be published.<sup>6</sup>

Reactogenicity refers to the expected, transient reactions occurring after vaccination and is common after COVID-19 vaccinations. The typical influenza-like symptoms (e.g. pain, fatigue, headache, chills and myalgia), are generally mild and self-limiting, lasting one to 3 days with few events observed after seven. It disproportionately burdens adults under 65, females, those with past COVID-19, or obesity.<sup>7</sup> Reactogenicity following COVID-19 vaccinations is important for perioperative management, as symptoms may prevent accurate assessment of surgical risk preoperatively, and may mimic symptoms of infection postoperatively.<sup>8</sup> Staff should be vigilant if a patient has been recently vaccinated, and any symptoms investigated to ascertain whether they stem from expected reactogenicity or surgical pathology (level II evidence).

Adverse events of special interest (AESI) are adverse events associated with COVID-19 vaccines or specific vaccine platforms. A range of AESI have been reported following vaccination, however for most it is unclear whether their incidence surpasses background rates, whether they have been clinically verified, or whether they are causally associated with COVID-19 vaccines. Presently, reported AESI with causal or suspected causal links to COVID-19 vaccines include Guillain-Barre syndrome (GBS),

myocarditis and pericarditis, and thrombosis with thrombocytopenia syndrome (TTS).<sup>9</sup> These generally occur within 2 weeks post vaccination. TTS has occurred more frequently after first doses of the Oxford-AstraZeneca vaccine, whereas myocarditis and pericarditis have occurred more frequently following second doses of the Moderna and Pfizer-BioNTech. Younger adults appear to be disproportionately affected, but risk factors remain to be fully elucidated. Current evidence suggests these events may be serious, but are extremely rare. If a surgical patient experiences adverse events related to COVID-19 vaccination, operative delay until resolution should be considered given potential alteration of cardiovascular and clotting functions (level II evidence).<sup>9</sup> Staff should familiarize themselves with current guidelines relating to TTS, GBS and myocarditis and pericarditis, so that required management can be optimized. Of note, thrombosis may be worsened in the presence of heparin due to enhanced platelet activation in TTS, hence heparins should be avoided and direct anticoagulants used instead (level II evidence).

Data from large clinical trials suggest that immunity against SARS-CoV-2 is generally reached between 7 days (Pfizer-BioNTech) to 14 days (Oxford-AstraZeneca, Gamaleya, Janssen, Moderna, Novavax, Sinovac and Sinopharm) following final vaccine dose.<sup>5</sup> Allowing at least 14 days after vaccination enables development of optimal immune responses, minimizing risk of nosocomial acquisition or transmission (level II evidence). Patients with immunological deficiencies or haematological malignancy may not develop protective immune responses following vaccination.<sup>3</sup> Regardless, rates of COVID-19 are dramatically higher for unvaccinated versus vaccinated persons, and vaccination should always be advised. Surgery and anaesthesia may dysregulate the immune system, an effect potentially persisting for some weeks.<sup>5</sup> This may in turn affect COVID-19 vaccine efficacy.<sup>5</sup> Booster vaccine doses may also be necessary at a population level as data suggest that vaccine-induced immunity wanes.<sup>10,11</sup> On average, vaccine efficacy or effectiveness against SARS-CoV-2 infection decreases from 1–6 months after full vaccination by over 20% across people of all ages.<sup>12</sup> This should be evidence-based and prioritized according to patient risk.

Crucial to safe clinical decision-making is patient stratification by operative urgency, level of morbidity and co-morbidities (level III-2 to IV evidence).<sup>13</sup> Case-by-case evaluation should incorporate: age; comorbidities associated with COVID-19-related risk such as hypertension, diabetes, cardiovascular or pulmonary disease, and immunocompromise; severity of surgical pathology; individual wishes; and likelihood of active SARS-CoV-2 infection (level III-2 to IV evidence).<sup>13</sup> As vaccination against COVID-19 significantly

decreases rates of acquisition and transmission, and outcomes are significantly poorer for patients with COVID-19 than those without,<sup>2</sup> vaccination should always be advised before elective surgery, and these patients prioritized ahead of the general population (level III-2 to IV evidence).<sup>14</sup> Elective surgery patients should be advised to have their COVID-19 vaccinations at least 14 days preoperatively (level III-2 to IV evidence).<sup>5</sup> Although considerably shorter than delay necessary to allow recovery after contracting COVID-19,<sup>15</sup> this time enables expected reactogenicity to pass, adequate immunity to develop, and most adverse events to be identified and managed. If this time period is allowed, any postoperative symptoms can be correctly identified as complications relating to the surgery or anaesthesia, rather than post-vaccination adverse effects (level III-2 to IV evidence).

Urgent and emergent operations should occur irrespective of COVID-19 vaccination status, as delays would likely significantly worsen patient outcomes (level III-2 to IV evidence). However, even in these circumstances efforts to ascertain the patient's vaccination and COVID-19 status should be taken to inform optimal management (level III-2 to IV evidence). Unvaccinated or incompletely vaccinated patients are at greater risk of acquiring and transmitting SARS-CoV-2 to surgical staff compared to fully vaccinated patients, and should be managed with greater caution (level III-2 to IV evidence). Similarly, those with immune deficiency may not be sufficiently immunized towards SARS-CoV-2 when presenting for surgery. Appropriate screening and testing for active SARS-CoV-2 infection should be undertaken preoperatively<sup>16</sup> and existing guidelines regarding personal protective equipment and other infection control methods should be adhered to regardless of patient vaccination status (level III-2 to IV evidence).

Determining an appropriate delay for vaccination following surgery is challenging due to current paucity of evidence. A pragmatic approach is required to ensure safe postoperative recovery and adequate immune responses. Appropriate delay should depend on the specific operation, particularly if any blood products, immunoglobulins or medications affecting immune function were administered (level III-2 to IV evidence). After undergoing major surgery, patients should complete the outlined postoperative management plan, and delay vaccination until their condition has stabilized or they have returned to expected functionality (level III-2 to IV evidence). For minor surgical procedures, the existing published guidelines advise waiting one to 2 weeks before vaccinating (level III-2 to IV evidence).<sup>5</sup> For any of the clinical statements made in this article that lack associated experimental or observational evidence, expert consensus-level evidence is provided. A limitation of this perspective piece and the associated recommendations is that at the current time, there are no appropriately designed studies that have measured the impact of vaccination on surgical outcomes.

As the global vaccine rollout continues, surgical staff will increasingly be faced with a patient population recently vaccinated against COVID-19. Significant disruption to surgical systems is projected to occur, particularly for elective operations.<sup>17</sup> There is demand from patients and staff to know how COVID-19 vaccination affects surgical planning, and when it is safe to operate following vaccination. It is imperative that future policy surrounding this topic is based on robust scientific evidence rather than relying on

eminent opinion,<sup>1</sup> particularly as substantial literature now exists underscoring safety and efficacy of existing COVID-19 vaccines and the development of immune responses. Vaccination should always be advised, as not vaccinating significantly worsens surgical outcomes at the individual<sup>2</sup> and population level (level II evidence). Receipt of booster doses should be based on the latest scientific data,<sup>10</sup> and should be advised for surgical patients, particularly as novel variants of the virus continue to arise (level II evidence). However, the effects of the COVID-19 vaccine on surgical planning require consideration to optimize clinical care. Patients should receive vaccinations at least 14 days prior to elective surgery to facilitate the resolution of reactogenicity symptoms, permit development of adequate immunity towards SARS-CoV-2 and allow adverse events to present and be managed (level III-2 to IV evidence). However, for urgent or emergency operations where patient outcome would be compromised by delay, surgery should proceed regardless of vaccination status (level III-2 to IV evidence). After surgery, delaying vaccination until the patient's condition has stabilized and their function has returned to anticipated levels is likely appropriate (level II evidence). Surgical systems can safely deliver effective care while the global community is vaccinated against COVID-19.

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