

New in Medicine Issue 125

October 2022

Editorial

Dear Colleagues

Recently US-FDA has authorized the use of two bivalent COVID-19 vaccines of Moderna and Pfizer-BioNTech for booster dose in younger individuals. These vaccines include an mRNA component of the original strain that provides an immune response protective against COVID-19 and an mRNA component in common between the omicron variant BA.4 and BA.5. It seems a timely intervention since children have gone back to school and the community has resumed pre-pandemic behaviors and activities. Another vaccine (Boostrix) to prevent the dangerous Whooping cough in infants (<2 months) has been approved by the FDA. It is given to the mother during the third trimester of pregnancy.

NICE has recently recommended Ozanimod for treating moderately to severely active ulcerative colitis in adults. This treatment regime is relevant only under conditions when the conventional treatment cannot be tolerated, is not working well enough, infliximab is not suitable, biological treatment cannot be tolerated or is not working well enough. Osteoarthritis (OA) is a common problem across the globe, and has become more relevant as it is now also seen in younger people. NICE has updated its earlier guidelines of 2014 for the care and management of OA. This updated guideline makes recommendations on diagnosing and managing OA, based on new evidence. This includes information and support, non-pharmacological and pharmacological treatments, follow-up, and referral for joint replacement.

In a recently published RCT in NEJM, a vitiligo drug, Ruxolitinib cream, was reported to result in a greater re-pigmentation of vitiligo lesions, and was associated with acne and pruritus at the application site. The Lancet published a randomised, open label, phase 3 trial on Rezvilutamide versus bicalutamide in combination with androgen-deprivation therapy in patients with high-volume, metastatic, hormone-sensitive prostate cancer (CHART). The two interim analyses found that Rezvilutamide plus ADT significantly improved radiographic progression-free survival and overall survival compared with Bicalutamide plus ADT in patients with high-volume, metastatic, hormone-sensitive prostate cancer, with a tolerable safety profile. In another phase3 trial, Pembrolizumab was found to significantly improve the disease-free survival compared to placebo and was not associated with new safety signals in completely resected, PD-L1-unselected, stage IB–IIIA non-small-cell lung cancers (NSCLC). Pembrolizumab is potentially a new treatment option for stage IB–IIIA NSCLC after complete resection.

Psoriasis is commonly seen in Dermatology practice and its treatment has been evolving. Oral Deucravacitinib was tested randomly, for moderate to severe plaque psoriasis, against Apremilast and placebo. Patients treated with Deucravacitinib were found to achieve at least 75 percent improvement in the Psoriasis area and Severity Index score, as compared to patients in the placebo or Apremilast groups. It was thus concluded that Deucravacitinib is an effective oral treatment for psoriasis for moderate to severe psoriasis in adults who are candidates for systemic therapy or phototherapy. Psoriasis may also be associated with Arthritis (PsA). The treatment of PsA involves the use of a variety of interventions, including many of the agents used for the treatment of patients with other forms of inflammatory arthritis, particularly spondyloarthritis and rheumatoid arthritis (RA), and others employed for the management of the cutaneous manifestations of psoriasis. Although a number of medications are effective in the treatment of both RA and PsA, trials involving some classes of biologic agents indicate that patients with RA and PsA can also experience markedly different responses to some drug classes. Treatment of the different elements of PsA includes coordinated intervention to address the major domains of the disease, including peripheral and axial arthritis, enthesitis, dactylitis, and skin and nail involvement.

A novel system for locating sentinel lymph nodes for breast cancer has been introduced recently. The Magtrace and Sentimag system (Endomag) comprises a magnetic liquid tracer (Magtrace) and a handheld magnetic sensing probe (Sentimag). It is both a magnetic marker and a visual dye. Magtrace is injected into the tissue beneath the areola or interstitial tissue around a tumour. The particles are then absorbed into lymphatics and become trapped in sentinel lymph nodes that can then be detected by the magnetic sensing probe and also by visualization to assist with biopsy.

*Dr Raju Vaishya
Professor and Senior Consultant
Department of Orthopedics
Indraprastha Apollo Hospitals, Delhi*

I. Drugs

FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups

Source: The FDA, October 2022

Link: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-bivalent-covid-19-vaccines>

The emergency use authorizations (EUAs) of the Moderna COVID-19 Vaccine, Bivalent and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent to authorize their use as a single booster dose in younger age groups.

FDA Approves Vaccine for Use during Third Trimester of Pregnancy to Prevent Whooping Cough in Infants Younger Than Two Months of Age

Source: The FDA, October 2022

Link: <https://www.fda.gov/news-events/press-announcements/fda-approves-vaccine-use-during-third-trimester-pregnancy-prevent-whooping-cough-infants-younger-two>

Boostrix (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed for immunization during the third trimester of pregnancy to prevent pertussis, commonly known as whooping cough, in infants younger than two months of age.

Ozanimod for treating moderately to severely active ulcerative colitis

Source: The NICE, October 2022

Link: <https://www.nice.org.uk/guidance/ta828>

Ozanimod is indicated for 'the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy.

II. Clinical Research

Two Phase 3, Randomized, Controlled Trials of Ruxolitinib Cream for Vitiligo

Source: The NEJM, October 2022

Link: <https://www.nejm.org/doi/full/10.1056/NEJMoa2118828>

Ruxolitinib cream resulted in greater repigmentation of vitiligo lesions than vehicle control through 52 weeks, but it was associated with acne and pruritus at the application site. Larger and longer trials are required to determine the effect and safety of ruxolitinib cream in patients with vitiligo.

Rezvilutamide versus bicalutamide in combination with androgen-deprivation therapy in patients with high-volume, metastatic, hormone-sensitive prostate cancer (CHART): a randomised, open-label, phase 3 trial

Source: The Lancet, October 2022

Link: [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(22\)00507-1/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(22)00507-1/fulltext)

In the two interim analyses, rezvilutamide plus ADT significantly improved radiographic progression-free survival and overall survival compared with bicalutamide plus ADT in patients with high-volume, metastatic, hormone-sensitive prostate cancer, with a tolerable safety profile.

Pembrolizumab versus placebo as adjuvant therapy for completely resected stage IB–IIIA non-small-cell lung cancer (PEARLS/KEYNOTE-091): an interim analysis of a randomised, triple-blind, phase 3 trial

Source: The Lancet, October 2022

Link: [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(22\)00518-6/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(22)00518-6/fulltext)

Pembrolizumab significantly improved disease-free survival compared with placebo and was not associated with new safety signals in completely resected, PD-L1-unselected, stage IB–IIIA NSCLC. Pembrolizumab is potentially

a new treatment option for stage IB–IIIA NSCLC after complete resection and, when recommended, adjuvant chemotherapy, regardless of PD-L1 expression.

Intensity-modulated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): 2-year toxicity results from an open-label, randomised, phase 3, non-inferiority trial

Source: The Lancet, October 2022

Link: [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(22\)00517-4/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(22)00517-4/fulltext)

2-year RTOG toxicity rates were similar for five fraction SBRT and conventional schedules of radiotherapy. Prostate SBRT was found to be safe and associated with low rates of side-effects.

Early prediction of treatment response to neoadjuvant chemotherapy based on longitudinal ultrasound images of HER2-positive breast cancer patients by Siamese multi-task network: A multicentre, retrospective cohort study

Source: The Lancet, October 2022

Link: [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(22\)00292-9/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00292-9/fulltext)

The SMTN was able to predict pCR in the early-stage of NACT for HER2-positive breast cancer patients, which could guide clinicians in adjusting treatment regimes.

Mortality of early treatment for radiation-induced brain necrosis in head and neck cancer survivors: A multicentre, retrospective, registry-based cohort study

Source: The Lancet, October 2022

Link: [https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370\(22\)00348-0/fulltext](https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00348-0/fulltext)

Among head and neck cancer survivors with RN, initiating treatment early after RN diagnosis is associated with a lower risk of all-cause mortality as compared with following the watch-and-wait policy, irrespective of whether patients exhibit symptoms or not.

Oral deucravacitinib for moderate to severe plaque psoriasis

Source: The Uptodate, October 2022

Link: <https://www.uptodate.com/contents/whats-new-in-dermatology>
https://www.uptodate.com/contents/treatment-of-psoriasis-in-adults?sectionName=Deucravacitinib&topicRef=87552&anchor=H1175374199&source=see_link#H1175374199

Adults with moderate to severe plaque psoriasis were randomly assigned to deucravacitinib, placebo, or apremilast. Patients treated with deucravacitinib were more likely to achieve at least 75 percent improvement in the Psoriasis Area and Severity Index score than patients in the placebo or apremilast groups. Deucravacitinib as an effective oral treatment for psoriasis for moderate to severe psoriasis in adults who are candidates for systemic therapy or phototherapy.

Immunohistochemical evaluation of E-cadherin in oral epithelial dysplasia and squamous cell carcinoma

Source: The IJPM, October 2022

Link: <https://www.ijpmonline.org/article.asp?issn=0377-4929;year=2022;volume=65;issue=4;spage=755;epage=760;aulast=Sharma>

Significant decrease in E-cad expression from dysplasia to poorly differentiated squamous cell carcinoma, suggesting that loss of expression of E-cad is closely related to the carcinoma.

HIF – 1 α as a marker of risk assessment for malignant transformation in oral submucous fibrosis: An immunohistochemical study

Source: The IJPM, October 2022

Link: <https://www.ijpmonline.org/article.asp?issn=0377-4929;year=2022;volume=65;issue=4;spage=761;epage=765;aulast=Sharma>

Progression and malignant transformation in OSMF is mediated by HIF-1 α in the background of fibrosis. Over expression of HIF-1 α may occur even before histologic evidence of angiogenesis or invasion. Hence, it can be used as a predictor for malignant transformation in OSMF.

A cross-sectional study of pre- and posttraining evaluation of inhaler use technique among outpatients with bronchial asthma or chronic obstructive pulmonary disease at a tertiary care hospital in India

Source: The PICR, October 2022

Link: <https://www.picronline.org/article.asp?issn=2229-3485;year=2022;volume=13;issue=4;spage=184;epage=188;aulast=Nitya>

Significant improvement in the correct use of inhaler technique post training. In addition, the most frequent error among inhaler users was revealed to be in the breath actuation.

III. Devices

Magtrace and Sentimag system for locating sentinel lymph nodes for breast cancer

Source: The NICE, October 2022

Link: <https://www.nice.org.uk/guidance/mtg72>

The Magtrace and Sentimag system (Endomag) comprises a magnetic liquid tracer (Magtrace) and a handheld magnetic sensing probe (Sentimag). Magtrace is intended for use only with the Sentimag system. Magtrace is a non-radioactive dark brown liquid containing superparamagnetic iron oxide with a carboxydextran coating. It is both a magnetic marker and a visual dye. Magtrace is injected into the tissue beneath the areola or interstitial tissue around a tumour. The particles are then absorbed into lymphatics and become trapped in sentinel lymph nodes that can then be detected by the magnetic sensing probe and also by visualisation to assist with biopsy.

IV. Treatment Guidelines

Osteoarthritis in over 16s: diagnosis and management

Source: The NICE, October 2022

Link: <https://www.nice.org.uk/guidance/ng226>

This guideline covers the diagnosis, assessment and non-surgical management of osteoarthritis. It aims to improve management of osteoarthritis and the quality of life for people with osteoarthritis.

Updated treatment guidelines for psoriatic arthritis

Source: The NICE, October 2022

Link: <https://www.uptodate.com/contents/whats-new-in-dermatology>
https://www.uptodate.com/contents/treatment-of-psoriatic-arthritis?sectionName=MTX%20use%20and%20efficacy&topicRef=87552&anchor=H3194559606&source=see_link#H3194559606

The guidelines use a domain-based approach that includes recommendations for peripheral arthritis, axial disease, enthesitis, dactylitis, skin psoriasis, and nail psoriasis. Important comorbidities and related conditions that may have a potential impact on treatment are also addressed. Our approach to the treatment of PsA is generally consistent with these guidelines.

V. Healthcare Administration

Predictive Ability of the Braden QD Scale for Hospital-Acquired Venous Thromboembolism in Hospitalized Children

Source: The JCI, October 2022

Link: [https://www.jointcommissionjournal.com/article/S1553-7250\(22\)00112-X/fulltext](https://www.jointcommissionjournal.com/article/S1553-7250(22)00112-X/fulltext)

The Braden QD Scale is a predictor for HA-VTE, outperforming its original intended use for predicting HAPI and performing similarly to other HA-VTE predictive models. As the Braden QD Total score is currently recorded in the electronic health records of many children's hospitals, it could be practically and easily implemented as a tool to predict which patients are at risk for HA-VTE.