NECA-Health Technology Reassessment Project

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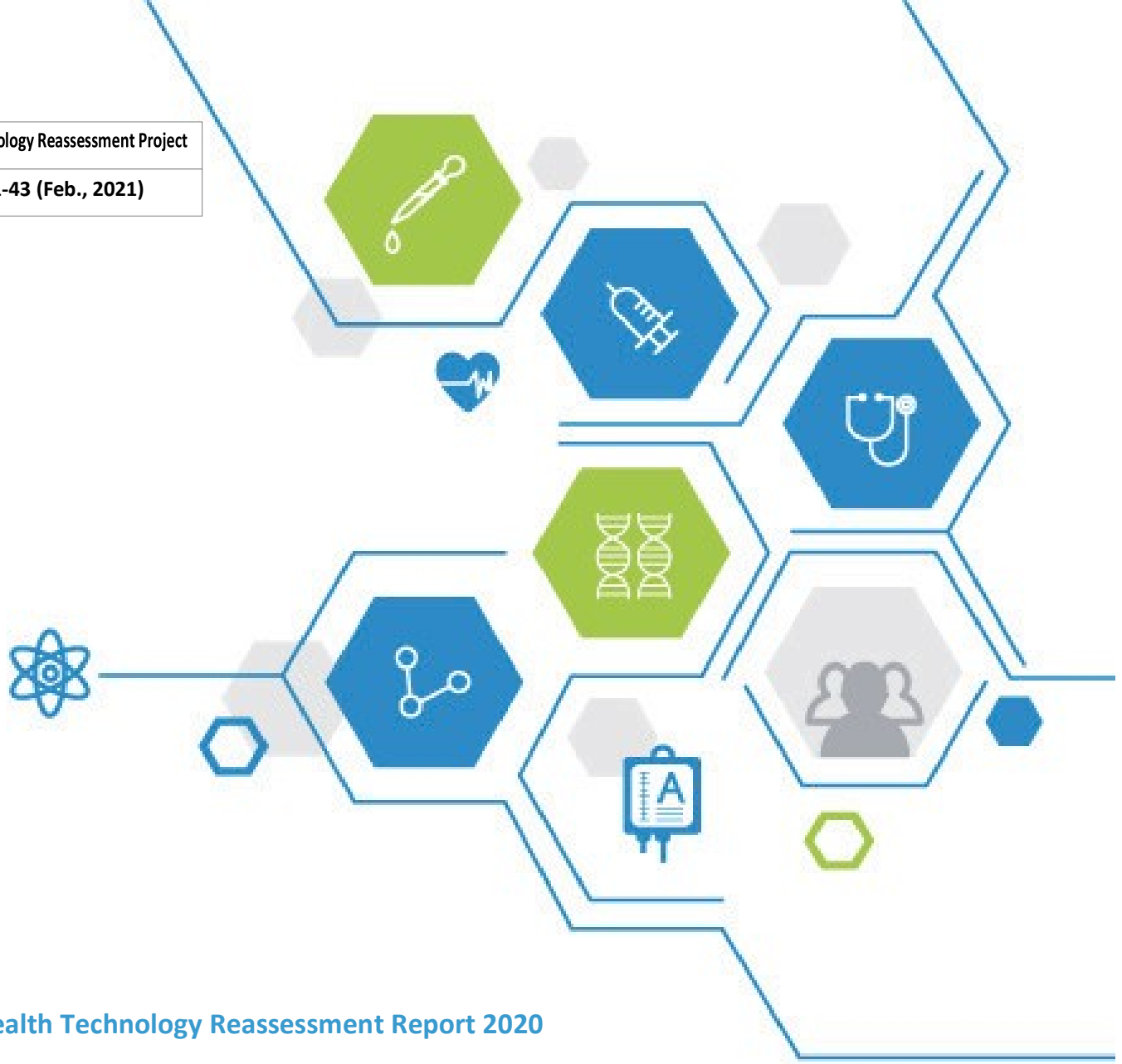

Health Technology Reassessment Report 2020

Digital Tomosynthesis(DTS) of the Chest

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Summary Statement

Background

The purpose of digital tomosynthesis(DTS) of the chest is to diagnose and follow-up thoracic lesions (except for breast lesion) in patient screened positive thereto. It was decided in the New Medical Technology Assessment Committee in May 2014 that digital tomosynthesis(DTS) of the chest is safe and valid. Therefore, as a result of internal monitoring, be re-assessed for safety and effectiveness.

Therefore, NECA brought the technology to the 8th Health Technology Reassessment Committee in 2020 (August 14, 2020) for re-assessment, in an attempt to induce appropriate use of medical technology and find the ground of efficient use of health and medical resources. Clinical safety and effectiveness results of such re-assessment were determined in the 2nd Health Technology Reassessment Committee in 2021 (Feb. 19, 2021).

Methodology

Systematic Review(SR) was conducted for assessment of safety and effectiveness of the technology. Taking into account the study's purpose, all methodologies were screened by the sub-committee in charge of assessing digital tomosynthesis(DTS) of the chest (the “sub-committee”) into confirmation.

The key Question of the above-mentioned SR was ‘How safe and effective is digital tomosynthesis(DTS) of the chest?’.

Based on the above-mentioned key Question, three different international literature databases and five different domestic literature databases were referred to in selection of literatures to be reviewed, under literature inclusion and exclusion criteria and by two separate reviewers. These two separate reviewers reached a consensus in that they perform risk of bias assessment on a separate basis, using RoBANS. Data extraction was also done by these two separate reviewers, also on a separate basis, using the pre-determined data extraction format. When they failed to reach a consensus, the third reviewer came into play for discussion. The collected data were not adequate for quantitative analysis; they were meta-analyzed by way of quantitative analysis. Evidence Level of the above-mentioned SR was determined by way of Grading of Recommendations Assessment, Development and Evaluation(GRADE).

Result

Safety and effectiveness of the technology was assessed by referring to a total of 23 literatures (16 retrieved for this study, 7 from the previous New Medical Technology Assessment). Out of those 23 literatures, 13 reported pulmonary nodule and the remaining 10 reported other thoracic lesions than pulmonary nodule. With the exception of 1 literature, all selected literatures used computerized tomography as the standard method of screening. Overall risk of bias assessed by QUADAS-2 was low.

Safety

Safety of digital tomosynthesis(DTS) of the chest was assessed by, as done for 15 different literatures, exposure rate (average effective dose). According to comparison of effective doses in chest X-ray and digital tomosynthesis(DTS) of the chest, all literatures without exception reported lower effective dose in digital tomosynthesis(DTS) of the chest than chest X-ray. Moreover, effective dose in digital tomosynthesis(DTS) of the chest was even lower than low-dose CT, evidencing the advanced safety of the technology. Considering exposure to dose in excess of 100mSv harms human body, it is considered safe when exposure to 1 to 2mSv of dose is used for medical purpose.

Effectiveness

Effectiveness of the technology was assessed in terms of, based on the indices used for the existing New Medical Technology Assessment, diagnostic accuracy, rate of (additional) lesion detected, radiographic assessment, time taken to read, impact on medical result (reduce in CT, reduced finding on chest X-ray), and patient-related factor (stand-by time, etc.)

As for effectiveness, diagnostic accuracy for both pulmonary nodule and thoracic lesions other than pulmonary nodule was not defined narrowly and reported in only few literatures. Therefore, it is to say that diagnostic accuracy as an index for assessment is not sufficiently grounded. However, the technology had marked advantage in detecting pulmonary nodule when compared to chest X-ray.

As for rate of (additional) lesion detected, the technology detected less lesions than chest CT in all literatures, implying that it is less effective than chest CT. However, in some literatures reporting detection of nodules over 5mm, the technology's ability to detect lesion was not different with statistical significance from that of chest X-ray. The technology had no statistically significant difference from chest X-ray in terms of radiographic assessment and time taken to read. It was also reported that the technology may partially replace some unnecessary CTs taken when viewed from the impact on medical result.

Conclusion and Suggestion

The sub-committee decided that the technology, involving exposure to only small dose of radiation, is more effective than chest X-ray, but less effective than chest CT. Therefore, it is decided that the technology can be considered as an effective, safe means of clinically detecting thoracic lesions in patient screened positive thereto.

With the above being said, the Health Technology Reassessment Committee recommends (Recommendation Grade I-b) limited use of the technology in patient screened positive to thoracic lesions by chest X-ray as clinically safe and purpose-oriented means of screening (Feb. 19, 2021).

Keywords

Thorax, Chest digital tomosynthesis, Radiation Effects, Diagnostic imaging