Syntermed IDS (Clinical Decision Support)

A Syntermed White Paper

As risk based payment models mature, every medical procedure, including diagnostic imaging, is under greater scrutiny and providers must be able to effectively demonstrate the value of procedures. Syntermed IDS is the first clinical decision support system to receive FDA 510(k) clearance for this kind of analysis in cardiology, and is designed to improve and maintain the highest quality interpretations and expedite workflow with faster reporting and more comprehensive reports.

What is Clinical Decision Support?

Clinical decision support is a key functionality of health information technology. When Clinical Decision Support is applied effectively, it increases quality of care, enhances health outcomes, helps to avoid errors and adverse events, improves efficiency, reduces costs, and boosts provider and patient satisfaction. Clinical Decision Support is not intended to replace clinician judgment, but rather to provide a tool to assist care team members in making timely, informed, and higher quality decisions. [Ref 1].

Why the change in ECTb v4?

The old compartmentalized model of calculating separate scores for a patient's different imaging studies (AC, NonAC, Prone, Thickening, …) made it difficult to get a clear picture of the overall status of the patient's myocardium. And, it didn't match how physicians actually interpreted and reported the study.

The new integrated model employed in ECTb v4 takes all of the imaging data into account when determining scores. This provides a more comprehensive picture of the status of the patient's myocardium and is more in line with how physicians actually interpret and report a study.

Quantified perfusion defect polar maps are still calculated and displayed after comparison to a normal file (as in ECTb v3); however, these static defect polar maps cannot integrate all of the clinical information. By employing certainty and information theory along with heuristic rules, IDS is able to integrate the clinical and imaging information and provide a comprehensive analysis of the study.

How does IDS work?

In order to overcome the errors and deficiencies resulting from statistical assumptions previously used for normalized myocardial perfusion distributions, IDS uses a novel non-parametric approach for

generating cumulative distribution functions of rest and stress, perfusion and thickening, for each of 17 segments encompassing the left ventricle for both normal populations and the current patient. A transfer function based on information theory then uses these distributions to transform the certainty that a segment is hypoperfused into a certainty factor (CF). The CF values for all segments in all categories form the input to IDS's set of over 230 heuristic rules which are used to reach a conclusion as to the myocardium's perfusion and functional status. These conclusions are automatically propagated to SmartReport, which then automatically generates a natural-language, structured report. For optimal accuracy of the diagnosis of Coronary Artery Disease (CAD), the diagnostician can use SmartReport to easily review the data and either modify and/or approve the report [Ref 2].

What are the differences between scores in ECTb v3 and ECTb v4?

In ECTb v3, the scores were based on the relative uptake of the tracer and the underlying normal file. After automatically quantifying perfusion, ECTb v3 used standard deviation maps to assign scores to the 17 regions. A sample in the middle of the LV chamber was taken; this value was translated into the number of standard deviations below the mean for each sample in the myocardium. Any region having a myocardial sample with standard deviation below this value was scored as 4, indicating perfusion is "absent". Likewise, the lower limit of normal in standard deviations below the mean is obtained for each myocardial sample. Any region having a myocardial sample with a standard deviation above this value was scored as 0, indicating it is "normal". The remaining standard deviation values used to define scores of 1, 2, and 3 were obtained by linear interpolation of the standard deviations assigned to 0 and 4. In ECTb v3, there could be up to 6 sets of scores for perfusion: stress, rest, reversibility, stress AC, rest AC and AC reversibility (thickening was not scored in ECTb v3).

As described in the previous section, ECTb v4 uses a separate normal file of cumulative distributions to calculate the certainty that a segment is hypoperfused. This certainty is then transformed into a certainty factor and mapped into a score from 0 – 4. These initial scores are then processed further by the 230 heuristic rules in IDS to come up with a final set of SmartScores. There are now 3 sets of perfusion SmartScores (stress, rest and reversibility), because IDS takes into account both AC (or prone) and NonAC when determining the final SmartScores. Additionally, there are now 2 potential sets of thickening SmartScores (stress and rest).

Validation

The diagnostic accuracy of the automatic SmartReport (generated by IDS) was tested in a prospective group of 1,000 patients (247 abnormal, 120 ischemic, 589 males) who had undergone a rest /stress ECG-gated Tc-99m conventional SPECT myocardial perfusion imaging study [Ref 3]. This validation consisted of comparing, in each patient, the detection of hypoperfusion at stress and the presence of inducible ischemia for each major vascular territory reported by SmartReport to those results from clinical reports generated by one of 9 possible nuclear cardiology experts which were used as the reference standard.

The overall accuracy for detecting disease was 77% and the overall accuracy for detecting ischemia was 84%. These results show promise that SmartReport may be used to automatically generate a structured natural language report in reduced time with a diagnostic performance comparable to those of nuclear cardiology experts.

We have also tested the diagnostic accuracy of the automatic SmartReport (generated by IDS) in 100 consecutive patients (36 abnormal,) who had undergone a stress/rest ECG-gated Rb-82 PET myocardial perfusion imaging study [Ref 4]. The overall sensitivity and specificity for detecting disease was 81% and 80% respectively. This preliminary data suggest that the overall diagnostic accuracy of IDS is high for Rb-82 myocardial perfusion 3D PET.

Potential discrepancy between quantitative polar maps and SmartScores

Because of the mathematical differences in how the quantitative polar maps are generated (statistical analysis) and how SmartScores are generated (non-parametric, probability analysis with additional heuristic rule refinement) there is the potential that a statistically significant perfusion defect may get a normal SmartScore or vice-versa (a statistically normal perfusion defect may get an abnormal SmartScore). This happens, not infrequently, when a physician's interpretation of a study does not match the quantitative polar maps. Such cases as artifact, where there is a statistically significant defect due to attenuation or processing problems; however, the physician recognizes these artifacts and calls the area normal (i.e. assigns a score of 0) even though the underlying quantitative polar maps show a defect. Or in the case of a subtle defect that isn't quite severe enough to reach statistical significance (i.e. no defect on the polar maps); however, the physician appreciates the subtleness of the defect and calls the area abnormal (i.e. assigns a score of 1-2) even though there is no underlying defect on the polar map. There are many reasons that this can happen; some examples are shown in the Example Cases section.

Sensitivity Setting in IDS

Another advantage of using a clinical decision support system like IDS is that the output can be tailored to be more sensitive or more specific, depending on the preferences of the physician. There are 3 such settings in IDS: Low (lower sensitivity, higher specificity), Medium (best combination of sensitivity and specificity) and High (higher sensitivity and lower specificity).

References

[Ref 1] http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/ClinicalDecisionSupport_Tipsheet-.pdf

[Ref 2] Garcia EV, Klein J, Esteves FP, Cooke CD, Manatunga D, Del'Aune C, Eppes R, Folks R. LVX: A Novel Decision Support System for Cardiac Image Interpretation and Reporting. J Nucl Cardiol Suppl 19(4):838, 2012.

[Ref 3] Garcia EV, Klein JL, Esteves FP, Del'Aune C, Cooke CD, Manatunga D, Verdes L, Folks R. Diagnostic Performance of a Smart Cardiac Reporting System for Myocardial Perfusion SPECT Imaging. J Nucl Cardiol Suppl 20(4):663, 2013.

[Ref 4] FP Esteves, R Sultana, C Cooke, RD Folks, EV Garcia. Diagnostic Accuracy Comparison of LVX Versus ECTb4 on Rest/Stress Rb-82 Myocardial Perfusion 3D PET. J Nucl Cardiol Suppl 20(4):689, 2013.