Exploration of a Bayesian Updating Tool to Provide Real-Time Safety Monitoring for New Medical Devices

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Abstract

Data Extraction and Longitudinal Time Analysis (DELTA) was developed to provide real-time safety monitoring of new devices and therapies. The tool utilizes Statistical Process Control (SPC) and Bayesian Updating Statistics (BUS) to conduct automated event rate monitoring and establish thresholds for alerting boundaries. A new medical device in a local interventional cardiology center was selected for a clinical example because it provided the necessary data infrastructure. This included a standardized data dictionary (American College of Cardiology National Cardiovascular Data Repository [ACC-NCDR]) and point of care data collection.

Background

Low event rates and rapid evolution of technology create challenges for safety monitoring in interventional cardiology. Bayesian updating statistical methodology (BUSM) provides an explicit method for the incorporation of previous information into risk estimates. Particularly in rare outcomes, this may allow the detection of safety issues earlier than a corresponding classical frequentist analysis. We explore the feasibility of a software monitoring tool that uses frequentist and Bayesian statistical methods independently and comparatively to detect significant changes in event rates.

System

DELTA imports a data stream in a flat file format from any source outcomes database. The source data used the ACC-NCDR data dictionary standard. This data, as well as study and trial configurations, were then stored in a Microsoft SQL 2000 server (Redmond, WA). A Microsoft IIS 5.0 web server and a web application developed in the Microsoft .NET environment served as the user interface. DELTA conducts simulated retrospective and prospective trials reported in monthly, quarterly, or yearly intervals. The results of this updating process are presented in summary format in tables and graphs available from the web interface (Figure 1).

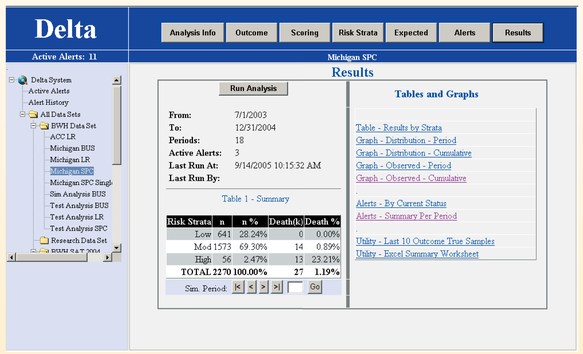

Figure 1: DELTA Results Screen Providing an Example of Layout and SPC Summary Options

Risk Strata	Sample #	Sample %	Deaths #	Deaths %
Low	641	28.24	0	0
Moderate	1573	69.30	14	0.89
High	56	2.47	13	23.21
Total	*2270*	*100.0*	*27*	*1.19*

Table 1: Local Institution Sample Data with Outcome of Interest (death) by Risk Strata

Example

2270 drug-eluting stent (DES) cases were analyzed from our local institution's catheterization lab database for the period of July 01, 2003 to December 31, 2004 for the outcome of death. The University of Michigan modeling study (Moscucci, et al. Circulation 2001) for bare-metal stents (BMS) provided the priors for each risk strata, as well as the risk stratification and scoring model for the analyses. These data were retrospectively evaluated in monthly periods. Sample size and outcome by risk stratum are shown in Table 1. Cumulative monthly event rates utilizing SPC are shown in Figure 2. Evolution of risk estimates for each time period in high risk stratum patients are shown below in Figure 3. SPC alerting boundaries were exceeded in the first month in the high risk stratum, and the BUS alerting boundaries were never exceeded. The alert in the SPC high risk stratum for the first month was because there was only one case which had the outcome (100%).

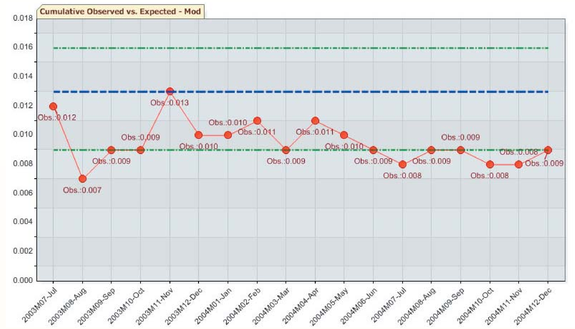

Figure 2: Moderate Risk Stratum SPC Cumulative Event Rates & Boundaries

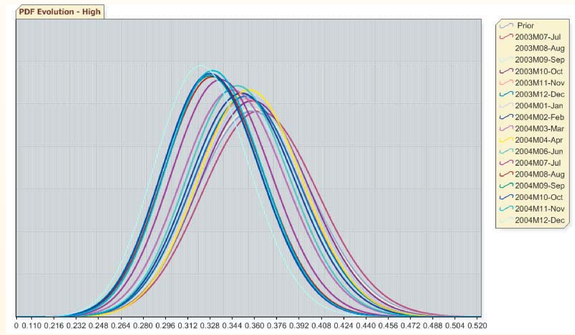

Figure 3: High Risk Stratum BUS Cumulative Event Rates & Boundaries

Conclusion

The system has been successfully evaluated on retrospective data for the outcome of death in DES cases. No alerts were generated indicating that the safety of the new DES device at our center was consistent with prior estimates from the BMS data. DELTA shows promise as a tool for prospective safety monitoring of new medical devices.