Advancing blood pressure and pulse data collection using electronic integration in a hypertension clinic- quality improvement measure.

Abstract

Aim:

To explore processing incoming multitudinal data on out-of- office blood pressure measurements.

Design & setting:

The study was undertaken in a clinical practice setting focused in the management of cohorts with diabetes and hypertension.

Method:

Practicing providers as a routine, repeatedly collected incoming data on patient's blood pressure, pulse and blood pressure and developing a conceptual scheme, working closely with data analysts to process the data through complimenting signal processing platform.

Result:

In this practical quality improvement project collection and processing real-world-data (RWD) in every day clinic can augment clinical management strategy through interconnected application platform.

Conclusion:

Home monitored blood pressure (HBP) data processing can lead to improve ranking blood pressure measures for provider interpretation with confidence. Furthermore, we find that more frequent monitoring and processing can facilitate access to more qualitative information leading to better patient involvement in treatment of care.

Introduction:

Hypertension is a major global burden and is a critical risk contributor to many cardiovascular diseases [1.] The higher the level above normal blood pressure the greater is the residual risk in hypertension. This is likely to increase as guidelines adopt lower optimum threshold (< 120 systolic and < 80 diastolic mmHg threshold compared to standard threshold of < 140 and < 90 mmHg.) [8, 31]. Therefore, there is need for attention to BP assessment, fidelity and objective reliability of estimates to improve risk categorization. Growing attention is given to blood pressure measurement outside clinical setting (ref 3,4). Ambulatory blood pressure measurement (ABPM) is accepted as gold standard in both detection and determination of control (Ref Shimbo New see below). Alternatively, home blood pressure (HBP) is economical and practical method in clinical

setting. The routine, integration of a processed information in to normal work flow might be desirable for better understanding on BP phenotype and components [1,2,3].

Telehealth is a practical method to engage and collect physiological blood pressure (BP) and pulse (P) data for patients. Traditionally these measurements are routine during clinic visits however, they are infrequent and insufficient observations to reliably support probability of effective control. The transmission of repeated self-observed blood pressure and pulse parameters to system level is common in daily clinical practice. However, there are no published article on customized report generation with stratified data estimates on BP, Pulse, components and concurrent coordinates much less, routine EMR integration to influence clinical practice workflow in the English literature.

We provide interconnected specific application systems with a unique platform to access patient generated BP and P data, tools and inherent algorithms for analysis of their components and creation of linear integrated reports to be seamlessly interfaced directly in the EMR. We conclude, collection of repeated data points of BP and P observations has enormous potential to be educational to end customers and other stakeholders.

Background

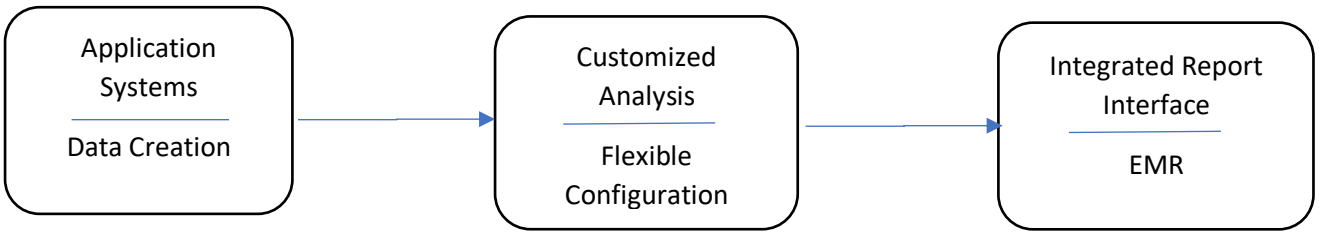
High blood pressure is highly prevalent disease and rates of control are suboptimal. A practical unmet challenge in clinical practice is operation to develop dependable estimate on clinic blood pressure. The threshold for definition for hypertension diagnosis has decreased and so is the impact on statistics [8]. In the US hypertension is the most common reason for office visit yet, the process remains ineffective to achieve effective control even when threshold for control is set higher [29]. In this background, home blood pressure monitoring (HBPM) has received increasing attention as reinforcement to empower disease management. Although there is real value to patient generated blood pressure (BP) and pulse (P) values incidental operational complexity in analysis of incoming data such as; verification, stratification of grades, detection of temporality and determination of probability distribution is a challenging task to work flow in every clinical setting. Therefore, in the clinics, routine collection of out-of-office physiological measurement and synthesis of data report can become information overload. In this article we provide an exemplar case report on data collection, analysis and integration done in every day clinical care. We propose in this article, operation system can be used to collect patient generated BP and P readings, assist appraisal of additional information to gain greater insight on BP components, P dynamics and improve disease detection and management.

The advances in digital technology have been very easy to support customers with limited skills. Besides, access to information from outside to clinics can be accomplished using personal devices fitted with application support operation. Leveraging these technical tools in clinical practice, it is

possible to access directly BP and P readings and analyze to assist interaction with patients. In this context self-monitored BP is well recognized to be very beneficial [2, 3, 4, 5, 6,7,8]

Methods

The hardware system design is a unified triangular platform interconnected for signal acquisition (application system) connected to signal conditioning platform (customized analysis function with flexible configuration) adoptive to interface integrated report in the electronic medical record (fig)



At the time of enrollment, all patients received education on how to monitor BP and P by the site coordinators, as well as operational details on accessing the data, messaging to the providers.

Technique:

To maximize adherence to monitoring, patients were told that their information would be reviewed by the clinicians responsible for managing blood pressure. To prevent any risk, patients were alerted to contact their clinicians directly with any urgent concerns.

Data collection method:

The required routine inclusion criteria for data collection and processing on blood pressure and pulse are device and cuff validation, minimum of 5 incoming readings a week. However, realistically being liberal to data collection is more practical hence, we encourage patients to adopt a practical scheme to collect data based on their lifestyle and work life balance.

It will be desirable to just provide if possible, on current # (406) patients adopting the protocol and their basic characteristics.

??.... collected patients whose primary diagnosis codes were Diabetes and Hypertension. We collected about 406 patients out of the total patients who were available for analysis. Total of 406 patients were eligible for analysis. Out minimum criteria for what ?? was to select atleast patients with a minimum of 100 readings per year submitted by the patient. If you plan to include this be specific and Adopted criteria for patient inclusion requires minimum of 5 readings a week. Table

1?? (where is the table) provides us the average value of all the demographic variables and the quantifiable variables that were used in our analysis. We also ensured prior to data collection and integration routine protocol included cuff validation, and device calibration for all patients considered in this study. Patients were encouraged to send minimum of 5 readings a week representing AM and PM observations. However, realistically being liberal to data collection is more practical hence, we encouraged patients to adopt a practical scheme to collect data to their best capabilities based on their lifestyle and work life balance. We collected data from 400 patients, who were required to have a minimum of 100 readings per year. (None of the afore mentioned data is presented in any part or form in this article graphics ???)

Data Processing and visualization on one exemplar patient.

At present there is no accepted standard for data fabrication and reporting on HBP measurements (HBPM). The representative set assembled below was adopted for practical value. Daily accessed readings are supported with main grid viewing frame with critical values on patient and population for required measure of response and also to be processed for regulated aggregation every week, month, quarterly and more in sequence. Details on raw data is summarized weekly with compressed previous estimates and coordinates made available in a pdf format. This is made readily available in the EMR for distribution across settings.

The Patient report showed in tabular format is shown in the Tables 2, 3, and 4.

Discussion

The guidelines for blood pressure measurement, detection and management are in a flux. BP targets are often defined by disease association adding additional level of complexity. There is urgent need for real life evidence. The agreement ABPM is superior, is globally accepted but is not practical tool for routine use (Ref Conen). The process of creating ideal and more real-life evidence is possible with HBPM

Technology allows one to generate RWD that can be very difficult to manually assemble and integrate in the EMR to augment clinical care. The process of encryption and cloud collection of abundant data can arrive in well-designed report form through operation system tools and assist virtual interaction in the clinic. Electronic platforms can support to perform several time-demanding tasks and display quality information on incoming patient's out-of-office BP and P readings. Patient generated BP and P readings reflect values collected unique to their setting. Unlike conditional infrequent clinic-based BP and P observations, out-office based BP and P measurement can be limitless and managed to reveal averages on multiple observations and derive hidden physiological BP components. Besides, the time integrated more frequent BP and P observations assists one to align relational value of these dynamics to ecological momentary changes. In clinical practice the demand to improve quality and quantity of data as a sustainable model is in need of a capacity building technical support with features to assist stakeholders needs.

The time demand to create usable report to gain benefit on incoming patient generated data is not practically effective to everyday workflow. In the clinic, improving the quality of report on incoming BP and P data requires validation, stratification, decomposition and analysis of components, and categorization at individual levels. This is difficult in the current clinical setting when the demand is to sacrifice face time. The process of care coordination and improvement in performance with effectiveness requires tool connecting patient and clinic with adaptive technical platforms to act as facilitators.

Patient's portal has been in use to enable the flow of raw data from patients to EMR. However, this web-based interaction is a technological challenge to patients who have limited resources. The commercially available programs are restricted to specific to disease conditions such as diabetes or distinctive to proprietary system level EMR platform (Epic-MyChart- Epic Systems, Verona, WI or automated Apple HelathKit- Apple Inc, Cupertino, CA). Besides, they are limited to perform fixed mediation role. Implementing user friendly platform to support individuals and population health in specific to disease conditions requires simplified data report architecture. This is possible through adoptive application independent of EMR and exchange designed report on incoming validated patient-generated data. Customizing information to support prevention, management and enable understanding emerging trends in risk detection requires innovative data processing and report assembly with expanded utility beyond point of clinical care.

The level of both systolic and or diastolic BP is clearly established as central to organ damage and are critical to control in prevention of any adverse events in clinical practice (Flint). There is accumulating evidence that increase variability of BP and P pressure is an additional cardiovascular risk factor (Parati, Selvaraj, Vidol-petiot, Pareek). It is not easy to translate these scientific evidences and implement routine measurement in a clinical setting as surrogate risk factor. The fine adjustment in BP control, assessment of novel parameters is difficult to adopt in any routine out patient clinical interaction. The reliability these parameters at individual level, requires repeated and reliable measurements. The operation system enabled analysis of self-monitored blood pressure (HBP) and P is a practical substitute to derive these components in clinical practice.

The hallmark to prevent external load on the arterial system is the key to this process to prevent cardiovascular events. The inhomogeneous transition of BP load and arterial properties, two interconnected processes are accepted as common biological behavior. Therefore, understanding concurrent changes in this mechanobiological process may have additional dimension to detect and clinical management.

The understanding of BP and P behavior from repeated measurement has made it possible to identify indirectly, bio-mechanical changes in the vasculature concurrent with changes in the blood pressure components with or absolute changes in the blood pressure. The description below is limited to activities and technical aspects used to collect components with potential. The value

attached to routine application of operation and clinical utility in the management of patients with or without illness requires confirmation.

The collection of data in research is a standardized and is less heterogeneous. The objective for assessment and aspects are different in clinical setting. The logistics in application of the process in the clinics for data collection and assembly is a complex hence, routine computational analysis individually, is not practical. The alternative is to adopt practical frame work to personalize analysis on self-monitored HBP for synthesis of report relevant to clinical setting. This is more reasonable for parameter estimate and prediction than wide scatter and insufficient data collected in clinical setting. The process of replication and validation makes this model well suited for detection of contrast change and extraction of additional parameters.

For the most part of the last century the recommended goals in hypertension control have focused on systolic and or diastolic BP (Munter). Systolic BP is a reflection of a combination of force generated by each left ventricular contraction and amplification in the artery at the level of pressure measurement. The pressure in the arteries in between each systolic ejection is due to a combination of remaining distending pressure and folding property of the artery at the site of pressure is measured. The change, circumferential instability in the arteries is the leading cause for cardiovascular morbidity and mortality. Aging, smoking, obesity, inactivity, diabetes, increasing blood pressure, kidney disease, abnormal lipids are some of the leading causes known to impact arterial instability (Younus).

Blood pressure variability

Variability of BP is intrinsic behavior with fluctuating BP dynamics and is a normal phenomenon. (Rothwell, Parati). Detection of magnitude of intraindividual variability has drawn considerable attention (Diaz,Wang). There seems to be independent and stronger association of variability with cardiovascular adverse events even more than MAP (Vida-petiot, Mehlum). There are range of variability assessment methods used in different research settings (Vishram,Gosmonova,Vida-petiot,Mancia,Mehlum,Mezue,Bangalore). These findings also recognizes importance of role of specific treatment strategy (Rothwell,Muntner,ALLHAT). This phenomenon is complex and is affected large number of variables. Hence, detection of magnitude of variability or average real varibility (ARV), understanding mean arterial pressure (MAP) around this variability and stiffness index (SI), peak to trough ratio (SI) can be valuable parameters. The application of different stipulated variability assessment and generation of complimentary risk information in every day clinical practice is difficult. (Ref Parati see below) Thus a new and operationally easy method may allow better understanding on its added value to routine clinic BP to guide clinicians in risk assessment.

Unlike BP pressure variability, loss P variability has been associated with decline in cardiovascular health (Ref…). Thus, linear analysis of change in variability in pulse may help to identify individual at risk.

Kalman filter process uses linear quadratic equalizer from the past data sets to provides the best estimate on the present state. In time series BP analysis this may aid one to gain insight in to inter current events.

Inference drawn in hypertension is often takes the from aggregation statistics. Distinguishable clinical events and best temporal aggregates on blood pressure is used to infer association. In this process latent clinical events and time series data on blood pressure may have the potential to help analysis and improve risk allocation than risk attribution. In hypertension, the process of approximation may potentially strengthen significance attached in its temporal changes. Kalman filter data on BP may assist in this process to understand latent clinical factors and change in time series or intercurrent changes in BP.

Conclusion

Clinical setting is less regular for information collection on dynamical physiological data. Collection of out of office blood pressure and pulse data will have distinctiveness and provide stronger relational value. It is technically possible now to assemble incoming physiological data with clarity and define categories to support clinical decision. The operation system also assists in designing the information on BP and P into subsets. These components are being recognized in research to be of value in detection individuals' clinical cardiovascular risk. The advancement of this approach and the emergence of knowledge will be a step to promote understanding BP components and trajectories in every day clinical management.

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Table 2 : Tabular report on time series (monthly)

Averages	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
ASBP	116	114	115	115	111	114	114	111	113	109	110	112
ADBP	70	72	73	73	70	71	69	67	68	65	66	60
AP	67	72	67	75	66	64	63	63	63	63	61	64
MAP	87.2	86.4	87.4	87.10	83.79	85.5	83.21	81.34	83.56	79.52	80.84	82.11

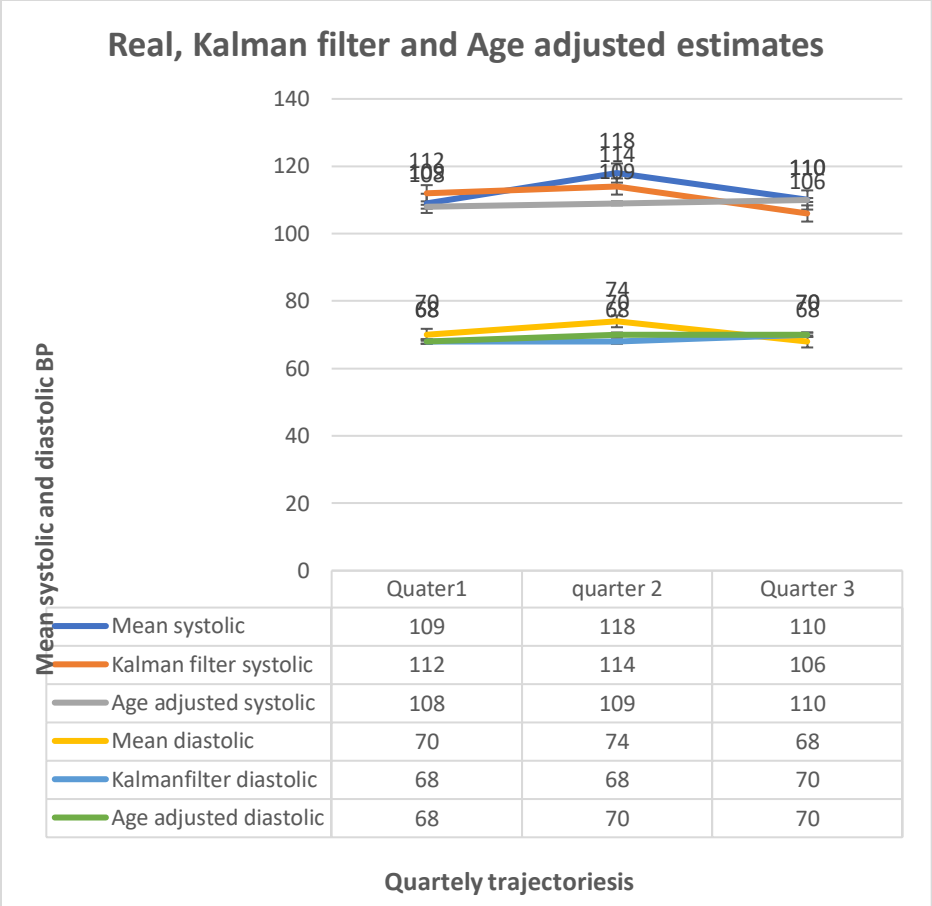
Table 3: Variability report (monthly)

SBPV	5.3	4.67	5.87	6.54	3.89	4.95	5.25	4.73	4.87	4.48	4.2	4.17
DBPV	3.04	3.02	3.92	4.19	2.74	3.23	3.58	2.99	3.23	3.43	3.19	2.66
PV	2.65	3.0	2.17	6.36	2.53	2.29	2.69	2.25	2.42	2.32	2.65	2.64

Table 4 : Pulse Dynamics (monthly)

PSR(SI)	1.41	1.69	1.53	1.35	1.28	1.72	1.62	1.62	1.42	1.29	1.37	1.41
HASI	0.5	0.65	0.57	0.45	0.39	0.66	0.62	0.62	0.5	0.4	0.47	0.5
s-HASI	0.29	0.41	0.15	0.35	0.26	0.23	0.42	0.38	0.3	0.22	0.27	0.29
MAP:PP	1.88	2.03	2.07	2.06	2.05	1.97	1.95	1.92	1.81	1.82	1.82	1.8

Table 5: Kalman filter with age adjusted estimates



	Quater1	quarter 2	Quarter 3
Mean systolic	109	118	110
Kalman filter systolic	112	114	106
Age adjusted systolic	108	109	110
Mean diastolic	70	74	68
Kalmanfilter diastolic	68	68	70
Age adjusted diastolic	68	70	70

Table 5

	Average Value
Age (years)	67.24
Male, %	47.25
Black, %	0
White, %	95.25

Systolic blood pressure (mm Hg)	123.86
Diastolic blood pressure (mm Hg)	71.7
Systolic blood pressure variability (mm Hg)	15.09
Body mass index (kg/m2)	31.90
Creatinine (mg/dL)	0.98
Glucose (mg/dL)	138.47
Sodium (mg/dL)	137.52
Thyroid stimulating hormone (mU/L)	2.14
Diabetes, %	71.74
Obstructive sleep apnea, %	9.14
Depression, %	0.27

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Table 1: Demographic information and average BP in 2014 and 2016 for treatment and control groups

	Treatment group	Control group	p-value
# of patients	726	907	
% Male*	46.14%	35.39%	<0.001
average age*	61.2 (15.4)	67.8 (16.4)	<0.001
% White	95.59%	95.59%	0.998
% Black	1.65%	2.09%	0.516
% Asian	0.55%	1.43%	0.081
% Other Race*	2.20%	0.88%	0.027
average BMI*	31.7 (6.81)	30.5 (7.45)	<0.001
% nonsmoker*	64.05%	58.65%	0.026
% former smoker	29.61%	30.54%	0.685
% light smoker (<10 per day)	1.10%	1.10%	0.999
% heavy smoker* (>10 per day)	4.96%	8.71%	0.003
% smoking status unknown	0.28%	0.99%	0.078
% nondrinker	49.31%	48.84%	0.851
% former drinker	0.41%	0.55%	0.691
% light drinker (<2 per day)	40.08%	37.05%	0.210
% heavy drinker (>2 per day)	0.96%	1.76%	0.173
% unknown drinker	9.23%	11.80%	0.095