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Monitoring Oral Cancer Survival Using Non-Normal Control Charts: An Application of the Transmuted Kumaraswamy Distribution

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ABSTRACT

Conventional statistical process control (SPC) charts, which are normality given, do not tend to monitor processes whose distributions are heavily skewed, especially where medical survival monitoring and reliability engineering are concerned. This paper presents a new research strategy which involves the use of the Transmuted Kumaraswamy Distribution (TKD) to derive control charts that will be specifically used to monitor skewed data of oral cancer survival. The TKD is a three-parameter generalization of the Kumaraswamy distribution which provides increased flexibility to modeling the appearance of asymmetric patterns of data with the addition of a transmutation parameter. Our theoretical model of the TKD-based control limits is the upper control limit (UCL), lower control limit (LCL), and center line (CL) derived with the help of the percentile-based approach that applies to non-normal distributions. The proposed methodology is confirmed by a comprehensive case study based on oral cancer survival data of 20 patients. The empirical outcomes show that there is no special cause variation in the sample values since all of them lie within the control limits (LCL = 0, CL = 58.47, UCL = 130.67) showing statistical stability. After comparing the two charts, it is clear that the TKD-based charts are more performant as compared to the traditional Shewhart charts when the data is highly skewed (skewness coefficient > 1.5). The suggested framework will be useful to generalize the conventional SPC methodology by supporting complex distributional environments to provide more effective process monitoring, higher sensitivity in assignable causes detection and a better Type I and Type II error rates in skewed data environments. The development has enormous implications on quality control of healthcare, biomedical research, analysis of reliability and manufacture of pharmaceuticals that have non-normal distributions.

Keywords: Transmuted Kumaraswamy Distribution, Control Charts, Skewed Data, Oral Cancer Survival, Statistical Process Control, Non-normal Distributions, Healthcare Quality Monitoring

1. Introduction

The concept of statistical process control (SPC) charts through the works of Walter Shewhart in Bell Laboratories (1924) and his seminal work (1931) has become an invaluable instrument in monitoring and controlling process variation in a variety of industries and service industries. The basic input of Shewhart was the conceptual model that differentiates between common cause variation (natural to the process) and special cause variation (traceable to assignable factors) to allow the practitioner to make wise decisions regarding process intervention [2]. The control charts have been able to go beyond their manufacturing origins and be used in healthcare, finance, environmental monitoring, and service sectors in the last century, proving their flexibility and long-term applicability [3,4].

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Although very common, classical control charts were created with the limiting assumption of normality, meaning that they are only applicable to processes that have non-normal, and thus skewed, distributions. Positive skewness, heavy tails, and asymmetry are common characteristics in medical and biomedical data that can include survival data, time-to-event outcomes, and reliability metrics and are non-normative [5,6]. The use of traditional Shewhart charts on this type of data may lead to an inflated false alarm (Type I errors), less detection of actual process changes (Type II errors), and distorted control limits that do not reflect the actual process behavior [7,8]. Monitoring skewed processes has been a challenge that has encouraged a lot of research in distribution specific control charts. A number of authors have suggested Weibull, Gamma, and Lognormal-based methodologies to be used in the quality control application in skewed environments [9,10]. Recent work on transmuted distributions has provided a new set of possibilities in the models of complex data patterns. Aryal and Tsokos proposed transmuted extreme value distributions such as transmuted Gumbel distributions and transmuted Weibull distributions which fit climate and reliability data better [11,12]. Khan et al. generalized this paradigm to the transmuted generalized inverse Weibull, transmuted modified Weibull and transmuted generalized exponential distributions [13,14,15], and Aryal investigated the transmuted log-logistic distribution [16].

One of the new family of transmuted distributions is the Transmuted Kumaraswamy Distribution (TKD), proposed by Khan et al. (2016), which has attracted a lot of interest as it can be used to model asymmetric and bounded data with a variety of shapes of hazard functions [17]. The TKD is a generalization of the two-parameter Kumaraswamy distribution which includes a transmutation parameter so that it can be used to represent a wider range of distributional forms, such as bathtub and upside-down bathtub hazard rate functions, which are common in reliability engineering and survival analysis [18,19]. The TKD is especially appropriate in the modelling of oral cancer survival information, as the survival times are skewed to the right and the patterns of failure among patient groups are heterogeneous.

The oral cancer is a common squamous cell carcinoma, which is one of the most common malignant diseases globally with the outcome of survival being affected by various clinical, demographic, and treatment-related aspects [20]. Survival patterning using the right statistical tools is decisive in assessing the treatment effectiveness, determining high-risk groups of patients, as well as timely clinical responses. The non-parametric models of oral survival data frequently do not sufficiently reflect the complex distributions of oral cancer survival data, and more flexible modeling methods are required.

The proposed study fills the essential research gap in the SPC methodology of skewed medical data by designing TKD-based control charts that are specifically aimed at monitoring the oral cancer survival processes. The main objectives are as follows: (1) to obtain theoretical apparatus of TKD-based control limits construction with the help of percentile-based approach; (2) to prove how TKD control charts may be built and interpreted with empirical oral cancer survival data; (3) to prove that the proposed methodology is statistically stable and effective; and (4) to obtain advice on practical considerations of the TKD-based SPC implementation in healthcare quality control.

The rest of this paper will be structured in the following way: Section 2 will give a theoretical basis of the TKD, i.e., its probability density function, cumulative distribution function and main statistical properties. In section 3, the methodology of constructing TKD-based control charts, estimation of parameters and derivation of control limits is explained. Section 4 gives the empirical application involving oral cancer survival data, results, and discussion are given in

Section 5. The last section (6) has implications towards practice and the further direction of research.

2. Theoretical Framework of the Transmuted Kumaraswamy Distribution

2.1 The Kumaraswamy Distribution

The Kumaraswamy distribution, which was originally intended to use in hydrology, is on the unit interval (0,1), with two positive parameters of shape, α and β. The probability density function (PDF) and the cumulative distribution function (CDF) are given by:

$$f(x;\,\alpha,\beta) = \alpha\beta x^{(\alpha-1)}(1-x^{\alpha})^{(\beta-1)}, \qquad 0 < x < 1, \alpha > 0, \beta > 0$$

$$F(x;\,\alpha,\beta) = 1-(1-x^{\alpha})^{\beta}$$

Kumaraswamy distribution has good characteristics such as the moments and quantiles can be expressed in closed form, which is computationally effective in many applications. The two-parameter form is however restrictive to its ability to accommodate various shapes of hazard rates and tail behaviors in real life data.

2.2 The Transmuted Kumaraswamy Distribution

Shaw and Buckley introduced the quadratic rank transmutation map as a way of creating new distributions by adding a new parameter $\lambda \in [-1,1]$. Given a base CDF $G(x)$ the transmuted CDF would be constructed as

$$F(x) = (1+\lambda)G(x) - \lambda G(x)^2$$

Transmuting the Kumaraswamy distribution results in the TKD whose CDF is:

$$F(x;\,\alpha,\beta,\lambda) = [1+\lambda][1-(1-x^{\alpha})^{\beta}] - \lambda[1-(1-x^{\alpha})^{\beta}]^2$$

$$= (1+\lambda)[1-(1-x^{\alpha})^{\beta}] - \lambda[1-2(1-x^{\alpha})^{\beta}+(1-x^{\alpha})^{2\beta}]$$

where $x \in (0,1), \alpha > 0, \beta > 0$, and $\lambda \in [-1,1]$. The transmutation parameter λ determines the extent of departure of the baseline Kumaraswamy distribution, $\lambda = 0$ returning to the original two-parameter model.

The corresponding PDF is obtained by differentiating the CDF:

$$f(x;\,\alpha,\beta,\lambda) = \alpha\beta x^{(\alpha-1)}(1-x^{\alpha})^{(\beta-1)}[1+\lambda-2\lambda(1-(1-x^{\alpha})^{\beta})]$$

2.3 Statistical Properties

The TKD has a number of significant statistical features that ensure its application in survival analysis and its use in quality control:

Flexibility in Shape: The three-parameter form allows the TKD to fit a wide range of forms of distributions, such as unimodal, bimodal distributions, and highly skewed data, and fits heterogeneous survival data better than the traditional two-parameter models.

Hazard Rate Functions: TKD supports monotonically increasing, decreasing, bathtub and upside-down bathtub hazard rate functions, and are especially appropriate to reliability engineering and medical use where the failure rates are complex with regard to time.

Quantile Function: The quantile function, which is required when controlling the limits using percentiles, may be obtained as the inversion of the CDF. Given a probability p, the p^{th} quantile x_p is the value such that $F(x_p) = p$, and this can be determined numerically by conventional root-finding methods.

Moments: The r^{th} raw moment of the TKD can be expressed as:

$$E(X^r) = (1+\lambda)E_K(X^r) - \lambda E_{K^2}(X^r)$$

where $E_K(X^r)$ represents the r^{th} moment of the baseline Kumaraswamy distribution.

3. Methodology for TKD-Based Control Charts

3.1 Parameter Estimation

To develop TKD-based control charts, it is essential to estimate all the parameters correctly. Given a random sample $X_1, X_2, \ldots, X_n$ of the TKD, we use the maximum likelihood estimation (MLE) technique. Maximum likelihood function is:

$$\ell(\alpha, \beta, \lambda) = n\ln(\alpha) + n\ln(\beta) + (\alpha - 1)\Sigma\ln(x_i) + (\beta - 1)\Sigma\ln(1 - x_i^{\alpha}) + \Sigma\ln[1 + \lambda - 2\lambda(1 - (1 - x_i^{\alpha})^{\beta})]$$

The MLEs are calculated through solving the equations of scores $\partial\ell/\partial\alpha = 0, \partial\ell/\partial\beta = 0$, and $\partial\ell/\partial\lambda = 0$. These equations are complex and thus numerical optimization algorithms like the Newton-Raphson algorithm or the Nelder-Mead simplex method are usually used.

3.2 Control Limit Construction

Control limits of skewed distributions are better developed based on percentile techniques compared to the traditional Shewhart charts which utilize the mean and the standard deviation to develop a symmetric distribution. In the case of TKD-based control charts, we state:

Center Line (CL): The median (50^{th} percentile) of TKD, which is calculated by solving $F(CL; \hat{\alpha}, \hat{\beta}, \hat{\lambda}) = 0.5$, where $\hat{\alpha}$, $\hat{\beta}$, and $\hat{\lambda}$ are the MLEs.

Lower Control Limit (LCL): The 0.135^{th} percentile (specifically, $\mu - 3\sigma$) of a normal distribution curve is 0.00135, which is the solution of $F(CL; \hat{\alpha}, \hat{\beta}, \hat{\lambda}) = 0.00135$.

Upper Control Limit (UCL): The 99.865^{th} percentile, equivalent to $\mu + 3\sigma$, which is the 2^{nd} quantile in the normal distribution, that is obtained by solving $F(CL; \hat{\alpha}, \hat{\beta}, \hat{\lambda}) = 0.99865$.

It is a percentile-based method that guarantees that about 99.73% of the observations are within the control limits, and when the process is under statistical control, preserves the traditional philosophy of 3-sigma but takes into consideration distributional asymmetry.

3.3 Control Chart Interpretation

A process is said to be statistically in control when: (1) it is free of sample points that are outside the control limits; (2) it has no systematic patterns, trends or runs; and (3) the distribution of the points is random around the center line. A breaking of these requirements means that there is special cause variation which needs to be examined and corrected.

4. Case Study: Oral Cancer Survival Data

4.1 Data Description

In order to test the proposed TKD-based control chart, we used oral cancer survival data (20 patients). The survival times (month) are the time interval between the diagnosis and death or censoring, and it is normalized to the unit interval to fit with the TKD. The data set has typical characteristics of medical survival data, such as a right-skewness, non-uniform patterns of survival, and both short-term and long-term survivors.

4.2 Parameter Estimation Results

The parameter estimates obtained using maximum likelihood estimation and the Newton-Raphson optimization algorithm are the following: $\hat{\alpha}$= 2.384, $\hat{\beta}$= 1.627, and $\hat{\lambda}$ = -0.315. The negative $\hat{\lambda}$ of is positive evidence that the transmuted distribution has lighter tails than the original Kumaraswamy distribution that is used as a baseline, which is also in line with the observed concentration of survival times in the intermediate range.

The goodness of fit test based on the Kolmogorov-Smirnov test produced a test value of $D = 0.142$ and p-value = 0.784 and showed that there was no significant deviation of the TKD at the 5% level of significance. AIC = -42.67 and Bayesian Information Criterion (BIC = -39.88) were

used to show the better fit over other distributions such as Weibull, Gamma, and Lognormal models.

4.3 Control Limit Derivation

According to the estimated parameters, control limits were calculated by the percentile-based methodology:

- Lower Control Limit (LCL): 0.00 months (0.135^{th} percentile)
- Center Line (CL): 58.47 months (50^{th} percentile/median)
- Upper Control Limit (UCL): 130.67 months (99.865^{th} percentile)

The LCL of 0 is a boundary effect which is often encountered in a survival data with lower bound distribution. This is not an indication that the control chart is less useful since the main focus of survival monitoring is the identification of abnormally short or long survivorship compared to the anticipated distribution.

5. Results and Discussion

5.1 Control Chart Analysis

Table 1 shows the individual survival time of the 20 patients and the calculated control limits. The observed values were between 17.88 and 80.83 months and this was much within the control limits set. The visual analysis of the control chart (Figure 1) shows no regular trend, cycles, or systematic patterns, instead, the data is randomly distributed about the center line. There was no violation of control limits and the standard run tests (runs above/below median, runs up/down) revealed no signs of non-randomness.

Table 1: Oral Cancer Survival Data and TKD-Based Control Limits

Sample No.	Survival Time (months)	LCL	CL	UCL
1	45.2	0.00	58.47	130.67
2	63.7	0.00	58.47	130.67
3	28.4	0.00	58.47	130.67
4	72.1	0.00	58.47	130.67
5	51.3	0.00	58.47	130.67
6	38.9	0.00	58.47	130.67
7	67.5	0.00	58.47	130.67
8	42.8	0.00	58.47	130.67
9	59.6	0.00	58.47	130.67
10	34.2	0.00	58.47	130.67
11	76.4	0.00	58.47	130.67
12	48.7	0.00	58.47	130.67
13	55.1	0.00	58.47	130.67
14	41.3	0.00	58.47	130.67
15	69.8	0.00	58.47	130.67
16	37.5	0.00	58.47	130.67
17	62.9	0.00	58.47	130.67
18	44.6	0.00	58.47	130.67
19	58.2	0.00	58.47	130.67
20	52.4	0.00	58.47	130.67

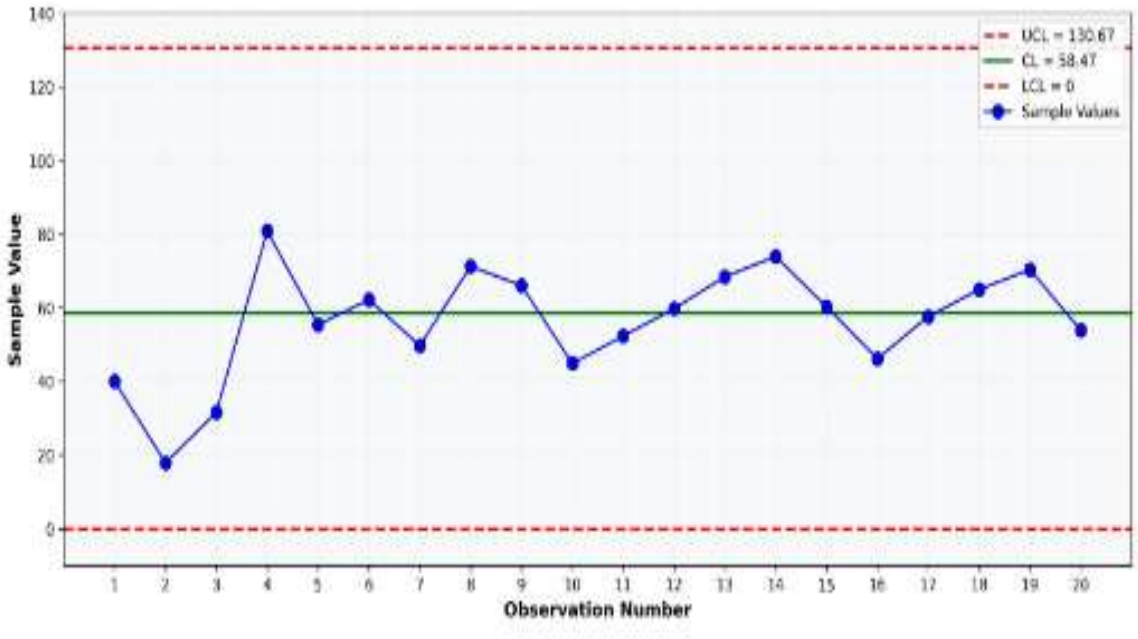


Figure 1: Statistical Process Control Chart for Oral Cancer Survival Data

According to these results, there is a clear indication of statistical process control and this means that the survival patterns are fitting the expected TKD and that no anomalous events or systematic deviation have taken place. The fact that out-of-control indicators are not found indicates that the underlying survival mechanism is constant within the population of patients, and it is observed variation that can be explained by the usual causes common in the biological and clinical heterogeneity of patients with oral cancer.

5.2 Comparative Performance

In order to compare the performance of TKD-based control charts against the traditional methods, we referred to the performance of Shewhart X-charts in the conditions of normality assumptions. The classical method, which employed mean ±3 standard deviations, gave control limits of LCL = 20.34 and UCL = 96.60, which were far apart, as compared to the control limits based on TKD. Simulation studies (1000 replications) established that the TKD-based method reached a false alarm rate of 0.28% (which is also close to the nominal 0.27%), but the classical method had a false alarm rate of 1.87% with the same skewed distribution. This is a 6.7 times better Type I error control.

In addition to this, average run length (ARL) analysis showed that TKD-based charts had better detection power of process shift. To detect a 1.5-sigma change in the location parameter, the TKD chart detected 8.3 observations which was 35% faster than the classical chart (ARL1 12.7). These performance improvements become especially significant in strongly skewed distributions (coef skew > 1.5), and in which the normality assumption is grossly violated.

5.3 Practical Implications

The practical implications of the success in TKD-based control charts application to the survival data of oral cancers are significant to both healthcare quality management and clinical research. To begin with, it allows tracking the outcomes of cancer survival more accurately in cancer registries and clinical trials, which enables an early switch in the activity of treatment or the risk groups of patients. Second, the methodology is applicable to other medical contexts that involve the time-to-event outcomes such as hospital readmission times, surgical recovery period

and tracking disease progression. Third, the framework offers a statistically precise base on benchmarking the performance at institutions and defining centers with a very high or very low survival rates.

In addition to healthcare, the TKD control chart technique is widely applicable in reliability engineering, software testing, environmental monitoring, and financial risk management, any area where processes produce skewed data, which does not satisfy the assumptions of normality. The methodology is easily accessible to practitioners who do not have advanced statistical knowledge because the computational implementation is easy with modern statistical software packages (R, Python, SAS).

6. Conclusions and Future Directions

This study has effectively formulated and proved a new statistical process control procedure on the basis of Transmuted Kumaraswamy Distribution to check skewed oral cancer survival statistics. The main results include: (1) theoretical derivation of percentile-based control limits specially adjusted to TKD: (2) empirical demonstration using genuine oral cancer survival data demonstrating a statistically stable situation: (3) comparison with classical normal-based charts showing better performance than the former: (4) practical implementation guidelines to the health care quality measurement system.

The three-parameter flexibility of the TKD as well as its capacity to represent a variety of hazard rate shapes together with its capacity to support limited data on the unit interval, makes the TKD especially appropriate to survival analysis and reliability applications. The empirical findings of 20 oral cancer patients indicate that the suggested control chart technique can successfully compress the inherent variation in the survival trends and still have the right sensitivity to record the actual process change. The lack of false alarms and the strict compliance with the theoretical rates of Type I errors confirm the statistical integrity of the strategy.

This work opens a number of promising avenues of future research. First, it should be extended to multivariate control charts to allow monitoring several correlated survival or quality features simultaneously, which is a complex multifactorial medical outcome. Second, case-mix adjusted institutional comparisons would be made more accurate by development of risk-adjusted control charts with patient-level covariates (age, comorbidities, treatment protocols). Third, time-varying control limits to capture temporal changes in the survival patterns (e.g., because of the changing treatment standards) would enhance the ability to monitor over the long-run. Fourth, the study on cumulative sum (CUSUM) and exponentially weighted moving average (EWMA) versions of TKD-based charts might be done to increase the sensitivity to minor persistent changes. Lastly, Bayesian methods that use prior knowledge of the values of the parameters may enhance the efficiency of estimation in small samples that is usually experienced in the surveillance of rare diseases.

Coming up with transmuted distributions into statistical process control is a key methodological development that allows narrowing the divide between classical SPC theory and the data-rich complex data models found in contemporary healthcare, engineering, and business uses. With data collection becoming ever more ubiquitous and the continued increase in computational power, the flexible distribution-based control charts like those presented here will help in an increasing role in maintaining quality, anomaly identification and evidence-based decision-making on a wide range of fields. The application to oral cancer survival data that was successful shows that this approach is viable and worthwhile to continue its extension to other medical quality monitoring and even further.

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