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# Tolerance interval for the mixture normal distribution

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**ABSTRACT**

Tolerance intervals (TIs) are widely used in numerous industries, ranging from engineering to pharmaceuticals. In these applications, it is commonly assumed that data are normally distributed. However, the normality assumption may not apply in many situations, such as in the case of multiple production lines. As a result, the mixture normal distribution may be a more applicable model than the normal distribution to fit real data. Although the conventional distribution-free TI can be adopted for the mixture normal distribution, it leads to an unsatisfactory coverage probability when the sample size is not sufficiently large. In this study, we propose two TIs for the mixture normal distribution. The first is based the expectation-maximization (EM) algorithm combined with the bootstrap method and the second is based on the asymptotic property of sample quantiles. The simulation results show that the proposed TIs have coverage probability closer to the nominal level than the distribution-free interval. A real engineering data example is used to illustrate the methods.

**KEYWORDS**

bootstrap method; distribution-free interval; EM algorithm; mixture normal distribution; quantile; tolerance interval

## 1. Introduction

A tolerance interval (TI), constructed based on a sample, is an interval expected to cover a fixed proportion of the population with a stated confidence. For example, an upper tolerance limit for a population with a given confidence level is such that a specified proportion or more of the population will fall below this limit (Meeker, Hahn, and Escobar 2017). By a similar definition, lower tolerance limits or TIs can be defined. TIs are widely used in industrial applications, such as in engineering and pharmaceutical industries (Hauck and Shaikh 2004; Kane 1986).

In the analysis of continuous data, TIs are useful for studying process capability, process reproducibility, and pharmaceutical dose uniformity (Hauck and Shaikh 2004; Kane 1986; Ryan 2007; Tsong, Shen, and Shah 2004). In these applications, data may usually be assumed to be normally distributed, and TIs for the normal distribution can be applied to these studies. In addition to continuous data, TIs are useful for analyzing discrete data, such as quality control of the number of defective units. Wang and Tsung (2009) and Cai and Wang (2009) have proposed improved TIs for Poisson and binomial distributions for quality control. Mathew and Young (2013) proposed fiducial-based TIs for discrete distributions. TIs for other parametric distributions can be found in Meeker, Hahn, and Escobar (2017), Wang and Tsung (2017), and Patel (1986).

Although TIs have been widely discussed in the literature, to the best of our knowledge, no study has focused on TIs for mixture distributions. In numerous applications, the mixture normal distribution may be more suitable than the normal model. For example, semiconductors are vital for modern electronics, such as light emitting diodes, computers, and cell phones. In the semiconductor industry, silicon wafers are the most common semiconductor material used in electronics for the fabrication of integrated circuits. The manufacturing process for silicon wafers is long, to guarantee the quality of semiconductor products, the process must be carefully monitored. Because this monitoring is conducted over numerous steps in the manufacturing process, data are usually bimodal or more complex. In this case, the mixture normal distribution is more appropriate to fit the data than the normal distribution. Because higher computational costs are involved in employing the mixture normal distribution than the normal distribution, it is difficult to derive an exact TI for the mixture normal distribution. The distribution-free TI is widely used when the data do not fit any parametric model or the TI is

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hard to obtain even though the data can fit a parametric model (Somerville 1958; Wilks 1942). Although the conventional distribution-free TI may be a naive approach, because the distribution-free TI can be applied to all continuous distributions, it may be too conservative for many distributions, such as the mixture normal distribution. Moreover, any error in the process may render the wafers useless, resulting in considerable loss in productivity; thus, such a process requires a high level of precision. From a simulation study, we revealed that the performance of the distribution-free TI for the mixture normal distribution was unsatisfactory in obtaining a high degree of accuracy when the sample size was not sufficiently large.

In this study, we propose two TIs for the mixture normal distribution. The first method combines the expectation-maximization (EM) algorithm and the bootstrap method and the second adopts the EM algorithm and the asymptotic distribution of a sample quantile to construct a TI. We compared the proposed TIs in the simulation study. Many criteria have been used to compare the TIs in the literature (Patel 1986), and the most frequently used is coverage probability. The coverage probability of a TI can be regarded as how the frequency of the TI captures a certain proportion or more of the population. A simulation study shows that the coverage probabilities of the proposed methods are closer to the nominal level than the distribution-free interval. Additionally, the second proposed TI outperforms the other TIs in most simulations.

This article is organized as follows. In Section 2, we review the key concepts involving TIs and the mixture normal distribution. Two proposed TIs are presented in Section 3. A simulation study comparing the performance of the TIs is detailed in Section 4. These methods are illustrated by a real data example in Section 5. Finally, a conclusion is provided in Section 6.

## 2. TIs and models

Let $X = (X_1, \dots, X_n)$ be random samples from $F_\theta(x)$, where $F_\theta(x)$ is the cumulative distribution function with an unknown parameter $\theta$. To find a TI for $F_\theta(x)$, we first review the definition of a TI. An interval $[L(X), U(X)]$ satisfying

$$P\{[F_\theta(U(X)) - F_\theta(L(X))] \geq \beta\} = 1-\alpha \qquad [1]$$

is said to be a two-sided $\beta$-content, $1-\alpha$confidence TI (i.e., $(\beta, 1-\alpha)$ TI) for $F_\theta(x)$. When $L(X)$ is replaced by $-\infty$ or $U(X)$ is replaced by $\infty$, the interval is called a $(\beta, 1-\alpha)$ upper tolerance limit or a $(\beta, 1-\alpha)$ lower tolerance limit for $F_\theta$. Furthermore, for the one-sided tolerance limit, a $(\beta, 1-\alpha)$ lower tolerance limit and a $(\beta, 1-\alpha)$ upper tolerance limit are equivalent to a $1-\alpha$ level lower confidence bound for the $(1-\beta)$th and $\beta$th quantiles of the distribution, respectively. Note that the left-hand side of Eq. [1] is the definition of the coverage probability of a TI.

The TI for the normal distribution has been widely discussed in the literature (Odeh and Owen 1980). First, we review the calculation of the exact TI for the normal distribution. Let $Y_1, \dots, Y_n$ be a random sample from the normal distribution with mean $\mu$ and variance $\sigma^2$. Let $\bar{Y}$ and $S^2$ denote the mean and variance of this sample. The exact $(\beta,\ 1-\alpha)$ upper- and lower-tolerance limits are

$$\bar{Y} + \frac{t_{1-\alpha}\left(n-1, \sqrt{n}z_\beta\right)}{\sqrt{n}} S,$$

and

$$\bar{Y} - \frac{t_{1-\alpha}\left(n-1, \sqrt{n}z_\beta\right)}{\sqrt{n}} S$$

respectively, where $t_{1-\alpha}(n-1, \sqrt{n}z_\beta)$ is the $(1-\alpha)$th quantile of a noncentral $t$ distribution with $n-1$ degrees of freedom and noncentral parameter $\sqrt{n}z_\beta$. The exact $(\beta,\ 1-\alpha)$ two-sided Tl for the normal distribution has the form $\bar{Y} \pm k_2 S$, where $k_2$ can be found in Meeker, Hahn, and Escobar (2017; Tables J.5a and J.5b). In this case, there is a closed form of the exact TI that exists for the normal distribution. Unlike in the normal distribution, we cannot find an exact closed form TI for the mixture normal distribution. First, we review the mixture normal distribution.A $k$-components mixture normal distribution has the probability density function

$$f_\theta(x) = \sum_{j=1}^{k} p_j g_{\mu_j, \sigma_j^2}(x), -\infty < x < \infty, \qquad [2]$$

where $g_{\mu_j,\sigma_j^2}(x)$ denotes the normal distribution with mean $\mu_j$ and variance $\sigma_j^2$, $p_j$denotes the weight of the $j$-th component, $\sum_{j=1}^{k} p_j = 1$ and $\theta = \{p_1, \dots, p_k, \mu_1, \dots, \mu_k, \sigma_1^2, \dots \sigma_k^2\}$.

A naive TI for the mixture distribution is the distribution-free TI, which is constructed based on order statistics and can be applied to most continuous distributions. Let $X_{(i)}$ denote the $i$th order statistic. A $(\beta, 1-\alpha)$ distribution-free TI has the form$[X_{(r)}, X_{(s)}]$, where $r$ and $s$ satisfy

$$P\left(F_\theta\left(X_{(s)}\right) - F_\theta\left(X_{(r)}\right) \geq \beta\right) \geq 1-\alpha. \qquad [3]$$

We generally choose $r$ and $s$ symmetrically or almost symmetrically within the ordered sample data.

According to Meeker, Hahn, and Escobar (2017), the exact coverage probability of the left-hand side of [3] is $P(Y \leq s - r - 1)$, where $Y$ follows a binomial distribution $B(n, \beta)$.

Although the distribution-free TI is a convenient approach, the performance of this method is not satisfactory. The coverage probability of the distribution-free TI can be much lower than the nominal level when the sample size is not large enough or the content $\beta$ is large. In some industry applications, the content of the TI is required to be close to one, such as 0.99 (ANSI/ASQ 2003 (COR)). In this case, unless the sample size is sufficiently large, the performance of the distribution-free TI is unsatisfactory. For example, to achieve a nominal coverage probability 0.95, the sample size of a two-sided $(0.99, 0.95)$ distribution-free TI must be greater than or equal to 473. When the sample size is 100 or 200, the coverage probabilities of the conventional two-sided $(0.99, 0.95)$ distribution-free TI are only 0.264 and 0.595, respectively, which are much lower than the nominal level 0.95. However, because of cost constraints, it is likely that the sample size will be less than 200 in real applications. Therefore, to overcome these unsatisfactory results caused by the distribution-free TI, we propose two TIs for the mixture normal distribution.

## 3. Main results

In this section, two TIs for the mixture normal distribution are proposed.

### 3.1. TI based on the bootstrap method

We first propose a method for constructing TIs based on the estimated mixture normal distribution, in which the parameter is estimated by the maximum likelihood estimator (MLE).

Let $\hat{\theta}$ denote the MLE of $\theta$. The EM algorithm is a widely used method for obtaining the MLE for the mixture normal distribution (Dempster, Laird, and Rubin1977). To apply the EM algorithm, we adopt the $k$ -means approach to set initial values of the parameters. Let $q_r \equiv F_{\theta}^{-1}(r)$ denote the $r$th quantile of the mixture normal distribution and let $\hat{q}_r$ denote the MLE of $q_r$. According to the invariance property, the quantile of this estimated mixture normal distribution is the MLE of the true quantile. Therefore, we have $\hat{q}_r = F_{\hat{\theta}}^{-1}(r)$.

We first construct a one-sided tolerance limit based on $\hat{q}_r$. By the property that the asymptotic distribution of the MLE approximates to the normal distribution (Casella and Berger 2002), we propose a $(\beta, 1-\alpha)$ lower tolerance limit

$$\hat{q}_{1-\beta} - z_{1-\alpha}\hat{s}_{1-\beta},$$

where $\hat{s}_{1-\beta}$ is the estimated standard error of $\hat{q}_{1-\beta}$ obtained by the bootstrap approach and $z_{1-\alpha}$ is the $1-\alpha$ upper cutoff point of the standard normal distribution. By a similar argument, a proposed $(\beta, 1-\alpha)$ upper tolerance limit is

$$\hat{q}_{\beta} + z_{1-\alpha}\hat{s}_{\beta}.$$

Using the one-side tolerance limit results, we propose a two-sided TI as

$$\left[\hat{q}_{\beta_L} - z_{1-\alpha/2}\hat{s}_{\beta_L}, \hat{q}_{\beta_U} + z_{1-\alpha/2}\hat{s}_{\beta_U}\right], \quad [4]$$

where $\beta_L = (1-\beta)/2$, and $\beta_U = (1+\beta)/2$.

The details of obtaining the terms in the interval [4] are provided in Procedure 1.

**Procedure 1**

**Step 1.** Use the $k$-means approach to classify the observed data $X_1, \ldots, X_n$ into $k$ clusters. Calculate the means and standard deviations for the $k$ clusters that are used as the initial values of $(\mu_1, \sigma_1^2), \ldots, (\mu_k, \sigma_k^2)$ in [2]. Set the initial values of $(p_1, \ldots, p_k)$ to be the proportion of data classified to each group.

**Step 2.** Use the initial values obtained in step 1 and apply the EM algorithm to obtain the MLE $\hat{\theta}$ for $\theta$.

**Step 3.** Find the $\beta_L$-th and $\beta_U$-th quantiles of the estimated mixture normal distribution $f_{\hat{\theta}}(x)$, which are $\hat{q}_{\beta_L}$ and $\hat{q}_{\beta_U}$, respectively.

**Step 4.** To obtain $\hat{s}_{\beta_L}$ and $\hat{s}_{\beta_U}$ of [4], generate a sample $y_1, \ldots, y_n$ from $f_{\hat{\theta}}(x)$, and adopt steps 1 and 2 to find the MLE based on the sample $y_1, \ldots, y_n$, which is denoted by $\hat{\theta}_{y_1,\ldots,y_n}$. Calculate the $\beta_L$-th and $\beta_U$-th quantiles $q_{\beta_L}{}^{y_1,\ldots,y_n}$ and $q_{\beta_U}{}^{y_1,\ldots,y_n}$ of the estimated mixture normal distribution $f_{\hat{\theta}_{y_1,\ldots,y_n}}(x)$.

**Step 5.** Repeat step 4 $m$ times to obtain $q_{\beta_U}^{y_1,\ldots,y_n(1)}, \ldots, q_{\beta_U}^{y_1,\ldots,y_n(m)}$ and $q_{\beta_L}^{y_1,\ldots,y_n(1)}, \ldots, q_{\beta_L}^{y_1,\ldots,y_n(m)}$. Let $\hat{s}_{\beta_U}$ and $\hat{s}_{\beta_L}$ be the sample standard deviations of $q_{\beta_U}^{y_1,\ldots,y_n(1)}, \ldots, q_{\beta_U}^{y_1,\ldots,y_n(m)}$ and $q_{\beta_L}^{y_1,\ldots,y_n(1)}, \ldots, q_{\beta_L}^{y_1,\ldots,y_n(m)}$, respectively.

**Step 6.** Combine the results of steps 1 through 5 to obtain TI [4].

### 3.2. TI based on the sample quantile

In this subsection, we propose another method for constructing a TI based on the asymptotic distribution of the sample quantile. Let

$$F_n(x) = \frac{1}{n}\sum_{i=1}^{n} I(X_i \le x)$$

denote the empirical distribution based on the sample $X_1, \ldots, X_n$, and $\tilde{q}_r \equiv F_n^{-1}(r) = \inf\{t | F_n(t) \ge r\}$ is the $r$-th sample quantile. By Serfling (1980), we have

$$\sqrt{n}(\tilde{q}_r - q_r) \to N\left(0, \frac{r(1-r)}{f_\theta(q_r)^2}\right). \quad [5]$$

Because $\theta$ and $q_r$ are unknown, to adopt Eq. [5] to construct a TI, we can replace $\theta$ and $q_r$ with $\hat{\theta}$ and $\hat{q}_r$. As a result, we have

$$L_q = \tilde{q}_{1-\beta} - z_{1-\alpha}\left(\frac{\beta(1-\beta)}{nf_{\hat{\theta}}(\hat{q}_{1-\beta})^2}\right)^{\frac{1}{2}} \quad [6]$$

and

$$U_q = \tilde{q}_\beta + z_{1-\alpha}\left(\frac{\beta(1-\beta)}{nf_{\hat{\theta}}(\hat{q}_\beta)^2}\right)^{\frac{1}{2}}, \quad [7]$$

as a $(\beta, 1-\alpha)$ lower tolerance limit and a $(\beta, 1-\alpha)$ upper tolerance limit for $F_\theta(x)$, respectively. From a simulation study, we found that, for a one-sided tolerance limit, the coverage probability of the lower tolerance limit [6] is always greater than or equal to that of the upper tolerance limit [7].

**Theorem 1.** The coverage probability $P(L_{1-\beta} < q_{1-\beta})$ is greater than or equal to $P(q_\beta < U_\beta)$ when $n$ is large.

The proof of Theorem 1 is given in the Appendix. To improve the coverage probability of the upper tolerance limit [7], we found that a slight modification of the upper tolerance limit [7] by replacing $\tilde{q}_\beta$with $\tilde{q}'_\beta$ can lead to a better result, where $\tilde{q}'_\beta = \inf\{t | F_n(t) \ge \beta + 1/n\}$. Therefore, the proposed $(\beta, 1-\alpha)$ upper tolerance limit and lower tolerance limit of the second method are

$$\tilde{q}'_\beta + z_{1-\alpha}\left(\frac{\beta(1-\beta)}{nf_{\hat{\theta}}(\hat{q}_\beta)^2}\right)^{\frac{1}{2}} \quad [8]$$

and [6], respectively.

For the two-sided TI, although we can directly use the lower limit [6] and the upper limit [8] as two limits, the performance is unsatisfactory. Thus, we propose a method by first using one of the two one-sided tolerance limits as a tolerance limit and then adjusting the other one. For the case of first using the lower tolerance limit, we use [6] as a lower tolerance limit, and then replace $\beta_U = (1+\beta)/2$ with

$$\beta_U^* = F_{\hat{\theta}}(L_q) + \beta. \quad [9]$$

Therefore, the proposed $(\beta, 1-\alpha)$ TI is

$$\left[\tilde{q}_{\beta_L} - z_{1-\alpha/2}\left(\frac{\beta_L(1-\beta_L)}{nf_{\hat{\theta}}(\hat{q}_{\beta_L})^2}\right)^{1/2}, \tilde{q}'_{\beta_U^*} + z_{1-\alpha/2}\left(\frac{\beta_U^*(1-\beta_U^*)}{nf_{\hat{\theta}}(\hat{q}_{\beta_U^*})^2}\right)^{1/2}\right]. \quad [10]$$

By a similar argument, we can first use [8] as an upper tolerance limit and replace $\beta_L = (1-\beta)/2$ by

$$\beta_L^* = F_{\hat{\theta}}(U_q) - \beta.$$

Therefore, the proposed $(\beta, 1-\alpha)$ TI is

$$\left[\tilde{q}_{\beta_L^*} - z_{1-\alpha/2}\left(\frac{\beta_L^*(1-\beta_L^*)}{nf_{\hat{\theta}}(\hat{q}_{\beta_L^*})^2}\right)^{1/2}, \tilde{q}'_{\beta_U} + z_{1-\alpha/2}\left(\frac{\beta_U(1-\beta_U)}{nf_{\hat{\theta}}(\hat{q}_{\beta_U})^2}\right)^{1/2}\right]. \quad [11]$$

The details of obtaining the second proposed TI are given in Procedure 2.

**Procedure 2**

**Step 1.** Follow steps 1 and 2 in procedure 1 to obtain the MLE for $\theta$.

**Step 2.** Use Eq. [6] to obtain a lower tolerance limit, Eq. [8] to obtain an upper tolerance limit, and Eq. [10] or Eq. [11] to obtain a two-sided TI.

## 4. Simulation

We conduct a simulation study to compare the proposed TIs with the distribution-free TI. In addition, we compare them with the exact TI for the normal distribution by assuming that the model is mis-specified to be a normal distribution. As stated in Section 1, the distribution-free TI exhibits drawbacks when the sample size is not sufficiently large or when the content $\beta$ is close to one. Because the high content case is crucial in industry applications, in this simulation study, we focus on the high content case. In this simulation, the level $(\beta, 1-\alpha)$ is set to be $(0.99, 0.95)$, and the sample size $n$ is set to be 20, 100, 200, 400, 1,000 and $m = 1000$.

In addition to comparing the coverage probabilities of these TIs, we also define the measure

$$\delta_1 = |\text{estimated limit} - q_\beta| \quad [12]$$

and

$$\begin{aligned}\delta_2 = &|\text{estimated lower limit} - q_{\beta_L}| \\ &+ |\text{estimated upper limit} - q_{\beta_U}|\end{aligned} \quad [13]$$

to compare the mean of the absolute difference between the exact quantile and the estimated limits of these TIs for the one- and two-sided TIs, respectively.

**Table 1.** Coverage probabilities of the $(0.99, 0.95)$ lower tolerance limit. The values in parentheses denote the standard deviation of the simulation.

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 0.947(0.003) | 0.175(0.005) | — | 0.703(0.006) |
| 100 | 0.955(0.003) | 0.634(0.007) | 0.803(0.006) | 0.943(0.003) |
| 200 | 0.954(0.003) | 0.864(0.005) | 0.851(0.005) | 0.941(0.003) |
| 400 | 0.939(0.003) | 0.980(0.002) | 0.921(0.004) | 0.946(0.003) |
| 1000 | 0.937(0.004) | 0.974(0.002) | 0.929(0.004) | 0.946(0.003) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 0.998(<0.001) | 0.179(0.005) | 0.739(0.006) | 0.821(0.005) |
| 100 | 0.999(<0.001) | 0.637(0.007) | 0.902(0.004) | 0.964(0.003) |
| 200 | 0.999(<0.001) | 0.869(0.005) | 0.917(0.004) | 0.959(0.003) |
| 400 | 0.999(<0.001) | 0.983(0.002) | 0.956(0.003) | 0.960(0.003) |
| 1000 | 0.999(<0.001) | 0.969(0.002) | 0.946(0.003) | 0.962(0.003) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 0.957(0.003) | 0.180(0.005) | — | — |
| 100 | 0.964(0.002) | 0.633(0.007) | 0.769(0.006) | 0.907(0.004) |
| 200 | 0.970(0.002) | 0.868(0.005) | 0.813(0.006) | 0.922(0.004) |
| 400 | 0.980(0.002) | 0.985(0.002) | 0.907(0.004) | 0.935(0.003 |
| 1000 | 0.987(0.001) | 0.971(0.002) | 0.914(0.004) | 0.941(0.003) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 0.999(<0.001) | 0.177(0.005) | 0.770(0.006) | 0.781(0.006) |
| 100 | 0.999(<0.001) | 0.637(0.007) | 0.902(0.004) | 0.964(0.003) |
| 200 | 0.999(<0.001) | 0.869(0.005) | 0.917(0.004) | 0.959(0.003) |
| 400 | 0.999(<0.001) | 0.982(0.002) | 0.947(0.003) | 0.960(0.003) |
| 1000 | 0.999(<0.001) | 0.972(0.002) | 0.944(0.003) | 0.959(0.003) |

**Table 2.** Values of $\delta_1$ for the $(0.99, 0.95)$ lower tolerance limit.

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 0.973(0.008) | 0.612(0.005) | — | 0.736(0.009) |
| 100 | 0.366(0.003) | 0.359(0.004) | 0.381(0.005) | 0.768(0.008) |
| 200 | 0.252(0.002) | 0.463(0.005) | 0.315(0.004) | 0.540(0.006) |
| 400 | 0.172(0.001) | 0.668(0.005) | 0.228(0.002) | 0.359(0.003) |
| 1000 | 0.103(0.001) | 0.294(0.002) | 0.147(0.001) | 0.218(0.002) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 3.451(0.014) | 0.819(0.007) | 1.060(0.012) | 1.243(0.014) |
| 100 | 2.022(0.005) | 0.459(0.006) | 0.567(0.005) | 1.036(0.009) |
| 200 | 1.742(0.004) | 0.589(0.007) | 0.406(0.004) | 0.696(0.006) |
| 400 | 1.566(0.003) | 0.835(0.007) | 0.302(0.003) | 0.471(0.004) |
| 1000 | 1.409(0.002) | 0.370(0.003) | 0.184(0.002) | 0.284(0.002) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 1.192(0.009) | 0.701(0.006) | — | — |
| 100 | 0.475(0.003) | 0.406(0.005) | 0.454(0.005) | 0.794(0.008) |
| 200 | 0.336(0.002) | 0.519(0.006) | 0.369(0.004) | 0.569(0.006) |
| 400 | 0.248(0.002) | 0.727(0.006) | 0.266(0.003) | 0.391(0.004) |
| 1000 | 0.166(0.001) | 0.325(0.003) | 0.169(0.002) | 0.242(0.002) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 5.544(0.019) | 0.746(0.007) | 0.975(0.011) | 1.110(0.013) |
| 100 | 3.432(0.007) | 0.402(0.005) | 0.546(0.005) | 0.963(0.008) |
| 200 | 3.044(0.005) | 0.513(0.006) | 0.393(0.004) | 0.634(0.005) |
| 400 | 2.788(0.003) | 0.717(0.006) | 0.272(0.002) | 0.423(0.003) |
| 1000 | 2.563(0.002) | 0.325(0.002) | 0.170(0.001) | 0.251(0.002) |

**Table 3.** Coverage probabilities of the $(0.99, 0.95)$ upper tolerance limit.

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 0.953(0.003) | 0.173(0.005) | — | 0.701(0.006) |
| 100 | 0.953(0.003) | 0.634(0.007) | 0.807(0.006) | 0.939(0.003) |
| 200 | 0.960(0.003) | 0.864(0.005) | 0.854(0.005) | 0.948(0.003) |
| 400 | 0.957(0.003) | 0.979(0.002) | 0.925(0.004) | 0.951(0.003) |
| 1000 | 0.958(0.003) | 0.971(0.002) | 0.929(0.004) | 0.956(0.003) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 0.988(0.001) | 0.183(0.005) | 0.801(0.006) | 0.759(0.006) |
| 100 | 0.999(<0.001) | 0.637(0.007) | 0.904(0.004) | 0.958(0.003) |
| 200 | 0.999(<0.001) | 0.869(0.005) | 0.913(0.004) | 0.955(0.003) |
| 400 | 0.999(<0.001) | 0.983(0.002) | 0.945(0.003) | 0.959(0.003) |
| 1000 | 0.999(<0.001) | 0.969(0.002) | 0.943(0.003) | 0.957(0.003) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 0.962(0.003) | 0.182(0.005) | — | — |
| 100 | 0.966(0.003) | 0.633(0.007) | 0.766(0.006) | 0.901(0.004) |
| 200 | 0.970(0.002) | 0.868(0.005) | 0.815(0.005) | 0.918(0.004) |
| 400 | 0.978(0.002) | 0.980(0.002) | 0.897(0.004) | 0.933(0.004) |
| 1000 | 0.985(0.001) | 0.974(0.002) | 0.912(0.004) | 0.939(0.003) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 0.998(<0.001) | 0.177(0.005) | 0.806(0.006) | 0.775(0.006) |
| 100 | 0.999(<0.001) | 0.637(0.007) | 0.902(0.004) | 0.959(0.003) |
| 200 | 0.999(<0.001) | 0.869(0.005) | 0.915(0.004) | 0.961(0.003) |
| 400 | 0.999(<0.001) | 0.982(0.002) | 0.949(0.003) | 0.958(0.003) |
| 1000 | 0.999(<0.001) | 0.969(0.002) | 0.945(0.003) | 0.960(0.003) |

**Table 4.** Values of $\delta_1$ for the $(0.99, 0.95)$ upper tolerance limit.

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 0.976(0.008) | 0.599(0.005) | — | 0.763(0.009) |
| 100 | 0.379(0.003) | 0.355(0.004) | 0.397(0.005) | 0.760(0.007) |
| 200 | 0.263(0.002) | 0.471(0.005) | 0.312(0.004) | 0.522(0.005) |
| 400 | 0.183(0.001) | 0.662(0.005) | 0.225(0.002) | 0.353(0.003) |
| 1000 | 0.113(0.001) | 0.287(0.002) | 0.146(0.001) | 0.221(0.002) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 2.836(0.016) | 1.017(0.009) | 1.210(0.013) | 1.426(0.016) |
| 100 | 1.406(0.006) | 0.637(0.007) | 0.669(0.007) | 1.300(0.011) |
| 200 | 1.129(0.004) | 0.748(0.008) | 0.509(0.005) | 0.859(0.007) |
| 400 | 0.953(0.003) | 1.035(0.008) | 0.355(0.003) | 0.588(0.005) |
| 1000 | 0.794(0.002) | 0.461(0.003) | 0.230(0.002) | 0.355(0.003) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 1.205(0.009) | 0.686(0.006) | — | — |
| 100 | 0.475(0.003) | 0.399(0.005) | 0.449(0.006) | 0.802(0.008) |
| 200 | 0.334(0.002) | 0.511(0.006) | 0.358(0.004) | 0.557(0.007) |
| 400 | 0.247(0.002) | 0.730(0.006) | 0.267(0.003) | 0.389(0.004) |
| 1000 | 0.167(0.001) | 0.328(0.002) | 0.173(0.002) | 0.237(0.002) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 5.499(0.019) | 0.743(0.007) | 1.010(0.012) | 1.085(0.013) |
| 100 | 3.445(0.007) | 0.417(0.005) | 0.553(0.005) | 0.957(0.008) |
| 200 | 3.058(0.005) | 0.522(0.006) | 0.394(0.003) | 0.622(0.005) |
| 400 | 2.795(0.003) | 0.726(0.006) | 0.270(0.002) | 0.419(0.003) |
| 1000 | 2.569(0.002) | 0.327(0.002) | 0.171(0.001) | 0.250(0.002) |

The coverage probabilities and the $\delta_1$ and $\delta_2$ values of these TIs are presented in Tables 1–8. Note that, in the small sample size case or when components have a large overlap, occasionally the EM algorithm may not converge. In these cases, we use the notation "—" in the tables.

Tables 1 and 2 present the results of the lower tolerance limit, and the results of the upper tolerance limit are shown in Tables 3 and 4. Tables 1 and 3 indicate that the coverage probability of the bootstrap method strongly depends on the precision of the parameter estimation. The modified sample quantile method is closer to the nominal level 0.95 compared with the distribution-free and bootstrap methods. Generally, the bootstrap method is superior to the distribution-free method. However, when the components $g_{\mu_j,\sigma_j^2}(x)$ of the mixture distribution [2] have a substantial overlap, the bootstrap method may not be more favorable than the distribution-free method

**Table 5.** Coverage probabilities of the $(0.99, 0.95)$ TI (10).

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 0.948(0.003) | 0.021(0.002) | — | 0.603(0.007) |
| 100 | 0.950(0.003) | 0.263(0.006) | 0.864(0.005) | 0.920(0.004) |
| 200 | 0.958(0.003) | 0.596(0.007) | 0.926(0.004) | 0.956(0.003) |
| 400 | 0.954(0.003) | 0.907(0.004) | 0.945(0.003) | 0.950(0.003) |
| 1000 | 0.945(0.003) | 0.970(0.002) | 0.969(0.002) | 0.954(0.003) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 0.996(<0.001) | 0.017(0.002) | 0.759(0.006) | 0.752(0.006) |
| 100 | 0.999(<0.001) | 0.267(0.006) | 0.956(0.003) | 0.958(0.003) |
| 200 | 0.999(<0.001) | 0.601(0.007) | 0.976(0.002) | 0.981(0.002) |
| 400 | 0.999(<0.001) | 0.912(0.004) | 0.985(0.002) | 0.978(0.002) |
| 1000 | 0.999(<0.001) | 0.969(0.002) | 0.994(<0.001) | 0.972(0.002) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 0.961(0.003) | 0.022(0.002) | — | — |
| 100 | 0.973(0.002) | 0.268(0.006) | 0.767(0.006) | 0.834(0.005) |
| 200 | 0.979(0.002) | 0.597(0.007) | 0.864(0.005) | 0.916(0.004) |
| 400 | 0.986(0.001) | 0.907(0.004) | 0.935(0.003) | 0.922(0.004) |
| 1000 | 0.996(<0.001) | 0.973(0.002) | 0.961(0.003) | 0.937(0.003) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 0.998(<0.001) | 0.019(0.002) | 0.797(0.006) | 0.716(0.006) |
| 100 | 0.999(<0.001) | 0.267(0.006) | 0.959(0.003) | 0.958(0.003) |
| 200 | 0.999(<0.001) | 0.600(0.007) | 0.982(0.002) | 0.981(0.002) |
| 400 | 0.999(<0.001) | 0.903(0.004) | 0.983(0.002) | 0.976(0.002) |
| 1000 | 0.999(<0.001) | 0.973(0.002) | 0.989(0.001) | 0.969(0.002) |

**Table 6.** Values of $\delta_2$ for the $(0.99, 0.95)$ TI (10).

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 2.119(0.017) | 1.583(0.009) | — | 1.755(0.019) |
| 100 | 0.762(0.006) | 0.714(0.005) | 0.997(0.010) | 1.475(0.013) |
| 200 | 0.509(0.004) | 0.680(0.006) | 0.798(0.008) | 1.214(0.009) |
| 400 | 0.348(0.003) | 0.881(0.007) | 0.640(0.005) | 0.743(0.006) |
| 1000 | 0.217(0.002) | 0.640(0.004) | 0.422(0.003) | 0.454(0.003) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 7.078(0.033) | 2.343(0.014) | 2.798(0.023) | 3.299(0.027) |
| 100 | 3.881(0.013) | 1.013(0.007) | 1.635(0.010) | 2.270(0.014) |
| 200 | 3.318(0.009) | 0.950(0.008) | 1.198(0.007) | 1.848(0.011) |
| 400 | 2.952(0.006) | 1.221(0.010) | 0.868(0.005) | 1.089(0.006) |
| 1000 | 2.660(0.004) | 0.886(0.006) | 0.545(0.003) | 0.638(0.004) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 2.607(0.020) | 1.791(0.010) | — | — |
| 100 | 1.002(0.007) | 0.791(0.006) | 1.079(0.010) | 1.513(0.014) |
| 200 | 0.713(0.005) | 0.746(0.006) | 0.903(0.008) | 1.263(0.010) |
| 400 | 0.525(0.004) | 0.956(0.007) | 0.741(0.006) | 0.793(0.006) |
| 1000 | 0.360(0.002) | 0.705(0.005) | 0.491(0.003) | 0.494(0.003) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 12.680(0.041) | 1.904(0.011) | 2.797(0.021) | 2.736(0.023) |
| 100 | 8.035(0.015) | 0.807(0.006) | 1.473(0.009) | 1.905(0.013) |
| 200 | 7.234(0.011) | 0.738(0.006) | 1.059(0.007) | 1.462(0.009) |
| 400 | 6.700(0.007) | 0.953(0.008) | 0.742(0.004) | 0.872(0.005) |
| 1000 | 6.266(0.005) | 0.706(0.005) | 0.456(0.002) | 0.520(0.003) |

because the EM algorithm may not precisely converge to the true parameter value.

Tables 5–8 present the results of the two-sided TIs. Table 5 shows that the coverage probabilities of the two-sided TIs obtained by fixing the lower limit and adjusting the upper limit, and Table 7 shows the coverage probabilities of the two-sided TIs obtained by fixing the upper limit and adjusting the lower limit. Unlike for one-sided tolerance limits, the modified sample quantile method is always better than the bootstrap method; for two-sided Tis, the modified sample quantile method is inferior to the bootstrap method in several cases. Note that, when the sample size is very small, both of proposed methods cannot achieve the nominal level (the coverage probabilities are approximately 0.7 to 0.8). However, these proposed methods still outperform the distribution-free method (the coverage probability is less than 0.1) when the components of the mixture normal distribution do not exhibit a substantial overlap.

**Table 7.** Coverage probabilities of the $(0.99, 0.95)$ TI (11).

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 0.948(0.003) | 0.018(0.002) | — | 0.614(0.007) |
| 100 | 0.950(0.003) | 0.263(0.006) | 0.861(0.005) | 0.921(0.004) |
| 200 | 0.958(0.003) | 0.595(0.007) | 0.926(0.004) | 0.938(0.003) |
| 400 | 0.954(0.003) | 0.907(0.004) | 0.947(0.003) | 0.940(0.003) |
| 1000 | 0.945(0.003) | 0.975(0.002) | 0.971(0.002) | 0.941(0.003) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 0.996(<0.001) | 0.017(0.002) | 0.759(0.006) | 0.762(0.006) |
| 100 | 0.999(<0.001) | 0.267(0.006) | 0.953(0.003) | 0.963(0.003) |
| 200 | 0.999(<0.001) | 0.593(0.007) | 0.977(0.002) | 0.969(0.003) |
| 400 | 0.999(<0.001) | 0.912(0.004) | 0.984(0.002) | 0.967(0.003) |
| 1000 | 0.999(<0.001) | 0.973(0.002) | 0.993(0.001) | 0.965(0.003) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 0.961(0.003) | 0.024(0.002) | — | — |
| 100 | 0.973(0.002) | 0.268(0.006) | 0.770(0.006) | 0.843(0.005) |
| 200 | 0.979(0.002) | 0.602(0.007) | 0.866(0.005) | 0.897(0.004) |
| 400 | 0.986(0.001) | 0.907(0.004) | 0.933(0.003) | 0.903(0.004) |
| 1000 | 0.996(<0.001) | 0.972(0.002) | 0.963(0.003) | 0.917(0.004) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 0.998(<0.001) | 0.021(0.002) | 0.792(0.005) | 0.710(0.006) |
| 100 | 0.999(<0.001) | 0.267(0.006) | 0.961(0.003) | 0.961(0.003) |
| 200 | 0.999(<0.001) | 0.595(0.007) | 0.981(0.002) | 0.966(0.003) |
| 400 | 0.999(<0.001) | 0.903(0.004) | 0.983(0.002) | 0.958(0.003) |
| 1000 | 0.999(<0.001) | 0.972(0.002) | 0.990(0.001) | 0.953(0.003) |

**Table 8.** Values of $\delta_2$ for the $(0.99, 0.95)$ TI (11).

| Sample size | Normal | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|---|
| $p = (1/3, 2/3), \mu = (0, 0.5), \sigma = (1, 1)$ | | | | |
| 20 | 2.119(0.017) | 1.583(0.009) | — | 1.765(0.019) |
| 100 | 0.762(0.006) | 0.714(0.005) | 0.997(0.010) | 1.476(0.013) |
| 200 | 0.509(0.004) | 0.680(0.006) | 0.798(0.008) | 1.227(0.009) |
| 400 | 0.348(0.003) | 0.881(0.007) | 0.640(0.005) | 0.799(0.006) |
| 1000 | 0.217(0.002) | 0.640(0.004) | 0.422(0.003) | 0.473(0.003) |
| $p = (1/2, 1/2), \mu = (0, 4), \sigma = (1.2, 1.5)$ | | | | |
| 20 | 7.078(0.033) | 2.343(0.014) | 2.798(0.023) | 3.277(0.026) |
| 100 | 3.881(0.013) | 1.013(0.007) | 1.635(0.010) | 2.301(0.014) |
| 200 | 3.318(0.009) | 0.950(0.008) | 1.198(0.007) | 1.886(0.011) |
| 400 | 2.952(0.006) | 1.221(0.010) | 0.868(0.005) | 1.212(0.007) |
| 1000 | 2.660(0.004) | 0.886(0.006) | 0.545(0.003) | 0.707(0.004) |
| $p = (1/4, 1/2, 1/4), \mu = (0, 1, 2), \sigma = (1, 1, 1)$ | | | | |
| 20 | 2.607(0.020) | 1.791(0.010) | — | — |
| 100 | 1.002(0.007) | 0.791(0.006) | 1.079(0.010) | 1.511(0.014) |
| 200 | 0.713(0.005) | 0.746(0.006) | 0.903(0.008) | 1.276(0.010) |
| 400 | 0.525(0.004) | 0.956(0.007) | 0.741(0.006) | 0.865(0.007) |
| 1000 | 0.360(0.002) | 0.705(0.005) | 0.491(0.003) | 0.518(0.003) |
| $p = (1/3, 1/3, 1/3), \mu = (0, 4, 8), \sigma = (1, 1.5, 1)$ | | | | |
| 20 | 12.680(0.041) | 1.904(0.011) | 2.797(0.021) | 2.707(0.023) |
| 100 | 8.035(0.015) | 0.807(0.006) | 1.473(0.009) | 1.903(0.013) |
| 200 | 7.234(0.011) | 0.738(0.006) | 1.059(0.007) | 1.463(0.009) |
| 400 | 6.700(0.007) | 0.953(0.008) | 0.742(0.004) | 0.920(0.005) |
| 1000 | 6.266(0.005) | 0.706(0.005) | 0.456(0.002) | 0.535(0.003) |

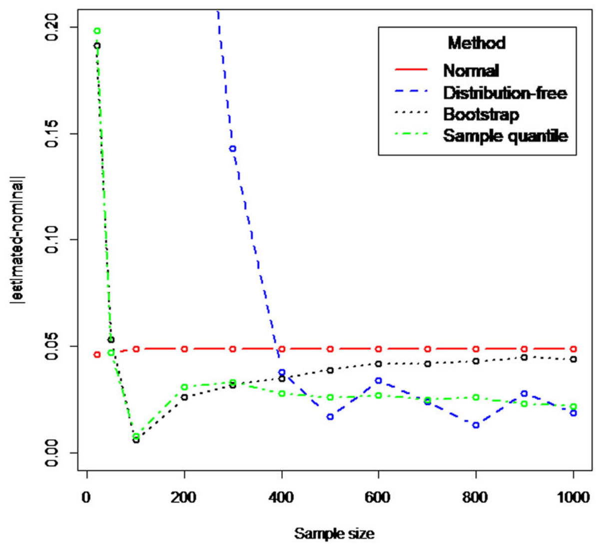


**Figure 1.** Absolute values of the difference between the coverage probability and the nominal level for the case of $p = (1/2, 1/2)$, $\mu = (0, 4)$, and $\sigma = (1.2, 1.5)$.

**Table 9.** Coverage probabilities of $(0.99, 0.95)$ TI (10), when the sample is sampling from the normal distribution.

| Sample size | Distribution free | Bootstrap | Sample quantile |
|---|---|---|---|
| $k = 1$ | | | |
| 20 | 0.021(0.002) | 0.913(0.004) | 0.934(0.004) |
| 100 | 0.265(0.006) | 0.969(0.003) | 0.985(0.002) |
| 200 | 0.601(0.007) | 0.974(0.002) | 0.976(0.002) |
| 400 | 0.909(0.004) | 0.978(0.002) | 0.963(0.003) |
| 1000 | 0.968(0.002) | 0.981(0.002) | 0.960(0.003) |
| $k = 2$ | | | |
| 20 | 0.019(0.002) | — | 0.594(0.007) |
| 100 | 0.263(0.006) | 0.851(0.005) | 0.916(0.004) |
| 200 | 0.603(0.007) | 0.915(0.004) | 0.964(0.003) |
| 400 | 0.907(0.004) | 0.942(0.003) | 0.948(0.003) |
| 1000 | 0.970(0.002) | 0.967(0.003) | 0.955(0.003) |
| $k = 3$ | | | |
| 20 | 0.022(0.002) | — | — |
| 100 | 0.267(0.006) | 0.762(0.006) | 0.826(0.005) |
| 200 | 0.592(0.007) | 0.867(0.005) | 0.909(0.004) |
| 400 | 0.912(0.004) | 0.929(0.003) | 0.913(0.004) |
| 1000 | 0.973(0.002) | 0.963(0.003) | 0.933(0.004) |
| $k = 4$ | | | |
| 20 | 0.017(0.002) | — | — |
| 100 | 0.266(0.006) | 0.691(0.007) | 0.763(0.006) |
| 200 | 0.599(0.007) | 0.827(0.005) | 0.872(0.004) |
| 400 | 0.910(0.004) | 0.898(0.004) | 0.901(0.004) |
| 1000 | 0.969(0.002) | 0.958(0.003) | 0.919(0.005) |

Under criteria [12] and [13], the bootstrap method outperforms the other methods. Although the distribution-free method occasionally has a more favorable performance when the sample size is not sufficiently large, the coverage probability is far away from the nominal level. The sample quantile method also provides good performance under these criteria. Additionally, the TI of the normal distribution is very conservative except when the components have a considerable overlap. The absolute values of the difference between the coverage probability and the nominal level for the case of $p = (1/2, 1/2)$, $\mu = (0, 4)$, and $\sigma = (1.2, 1.5)$ from Table 5 are plotted in Figure 1.

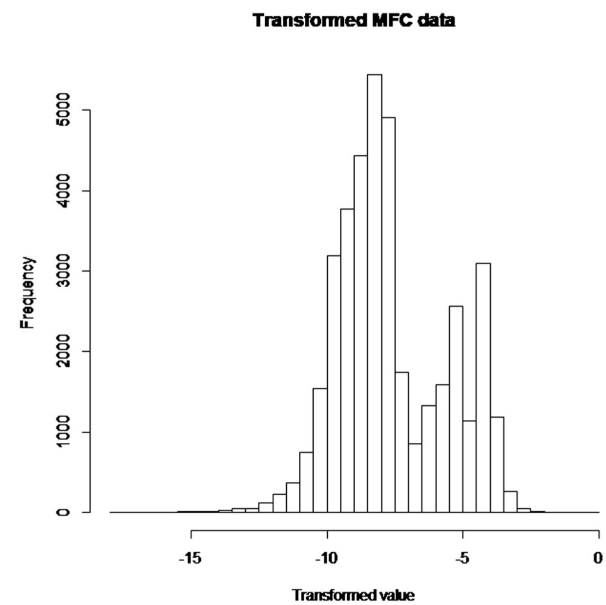


**Figure 2.** Transformed data of the MFC.

In our simulation study, because the performances of the bootstrap method and the modified sample quantile method strongly depend on component overlap, to ensure that the bootstrap method and the modified sample quantile method can compete similarly with the distribution-free method, we consider a worst case for the bootstrap method and the modified sample quantile method. In the considered case, the true model is the normal distribution but we mis-specify it to be the mixture normal distribution. These TIs or tolerance limits were compared for this case. The simulation results in Table 9 show that the two proposed methods are still superior to the distribution-free method in the extreme cases.

## 5. Real data example

In this section, we use a mass flow controller (MFC) example as a real data example to illustrate our methods and compare these approaches. An MFC is a device used to measure and control the flow of liquids and gases. The MFC data $x_j, j = 1, \ldots, 232651$ were recorded every second of a producing process at the Industrial Technology Research Institute of Taiwan. There is a corresponding setting value $v_j$ for each $j$. The relative error of the data is defined as $e_j = (x_j - v_j)/v_j$. Engineers are required to determine whether 99 percent of the relative error is within a specified limit. Both the mean and standard deviation of $e_j$ are crucial variables for determining whether the process is stable. In this example, we inspected the

**Table 10.** $(0.99, 0.95)$ TIs based on all MFC data.

| Component number | Normal | Distribution free | Bootstrap method | Modified sample quantile |
|---|---|---|---|---|
| 8 | [0, 0.0567] | [0, 0.0288] | [0, 0.0265] | [0, 0.0284] |

**Table 11.** Coverage probabilities of four different $(0.99, 0.95)$ upper tolerance limits.

| Sample size | Number of components | Normal | Distribution free | Bootstrap method | Modified sample quantile |
|---|---|---|---|---|---|
| 150 | 2 | 0.999 | 0.784 | 0.977 | 0.958 |
| | 3 | 0.999 | 0.779 | 0.974 | 0.955 |
| | 4 | 0.999 | 0.782 | 0.912 | 0.866 |
| 200 | 2 | 0.999 | 0.870 | 0.982 | 0.956 |
| | 3 | 0.999 | 0.864 | 0.986 | 0.971 |
| | 4 | 0.999 | 0.867 | 0.913 | 0.899 |
| 250 | 2 | 0.999 | 0.921 | 0.989 | 0.968 |
| | 3 | 0.999 | 0.912 | 0.986 | 0.966 |
| | 4 | 0.999 | 0.917 | 0.917 | 0.926 |

variable $y_i = |E_i|$ for each minute, where

$$E_i = \frac{1}{60} \sum_{j=60(i-1)+1}^{60i} e_j, \quad i = 1, \ldots, \lfloor N/60 \rfloor$$

$E_i$ is considered instead of $e_j$ because the value of $e_j$ is occasionally very large at some time point, but the production process can still run smoothly in this case. To avoid obtaining a biased result due to these outliers, we use the average values $E_i$ in the analyses.

Here we consider the log transformation $h_i = \ln(y_i)$ of $y_i$ instead of $y_i$ because $h_i$ can fit a mixture normal distribution better than $y_i$, and the histogram of $h_i$ (Figure 2) shows that the mixture model is more suitable than the normal model. To fit the mixture normal distribution, we use the Akaike information criterion (AIC) and the Bayesian information criterion (BIC) to select the component number. The optimal component numbers are both eight by the AIC and BIC, respectively. We first obtain $(0.99, 0.95)$ level TIs based on these two component numbers for $h_i$, and then take the exponential of them to obtain TIs for $y_i$. The $(0.99, 0.95)$ TIs are presented in Table 10.

In addition, we use this data example to compare these methods. We conduct a simulation study on this data set with a sample size of 150, 200, and 250. We adopt AIC and BIC to select models for the sampled data. The AIC values decrease slowly when the component number is greater than two, and they are very close in most cases when the component numbers are four and five. The BIC values reveal that the two-component model is preferable. Therefore, we calculate the coverage probabilities of these methods with the component number from two to four. The results are shown in Table 11.

## 6. Conclusions

In this study, we propose two methods for constructing tolerance limits and TIs for the mixture normal distribution and compare these methods with the conventional distribution-free method and the TI for the normal distribution. When the sample size is not large, the coverage probability of the distribution-free method is usually much lower than the nominal level. The two proposed methods generally outperform the distribution-free TI and the TI for the normal distribution when the sample size is not large or the content $\beta$ is large. The modified sample quantile method has better coverage probability than the bootstrap method in most simulation cases.

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## Appendix

**Proof of Theorem 1.** According to the definition of $\tilde{q}_r$, there exist positive integers $r$ and $s$ such that $\tilde{q}_{1-\beta} = X_{(r)}$, and $\tilde{q}_\beta = X_{(s)}$. The coverage probability of $L_{1-\beta}$ is

$$\begin{aligned}
&P(L_{1-\beta} < q_{1-\beta}) \\
&= P\left(X_{(r)} \le q_{1-\beta} + z_{1-\alpha}\sqrt{\frac{\beta(1-\beta)}{nf_{\hat{\theta}}^2(\hat{q}_{1-\beta})}}\right) \\
&= \sum_{k=r}^{n}\binom{n}{k}\left[F_\theta\left(q_{1-\beta} + z_{1-\alpha}\sqrt{\frac{\beta(1-\beta)}{nf_{\hat{\theta}}^2(\hat{q}_{1-\beta})}}\right)\right]^k \\
&\left[1 - F_\theta\left(q_{1-\beta} + z_{1-\alpha}\sqrt{\frac{\beta(1-\beta)}{nf_{\hat{\theta}}^2(\hat{q}_{1-\beta})}}\right)\right]^{n-k} \\
&= 1 - P(Y_L \le r-1),
\end{aligned} \qquad [A.1]$$

where $Y_L$ follows a binomial distribution$B(n, p_L)$ and

$$p_L = F_\theta\left(q_{1-\beta} + z_{1-\alpha}\sqrt{\beta(1-\beta)/nf_{\hat{\theta}}^2(\hat{q}_{1-\beta})}\right).$$

Similarly, the coverage probability of $U_\beta$ is

$$\begin{aligned}
&P(U_\beta > q_\beta) \\
&= P\left(X_{(s)} > q_\beta - z_{1-\alpha}\sqrt{\frac{\beta(1-\beta)}{nf_{\hat{\theta}}^2(\hat{q}_\beta)}}\right) \\
&= 1 - P\left(X_{(s)} \le q_\beta - z_{1-\alpha}\sqrt{\frac{\beta(1-\beta)}{nf_{\hat{\theta}}^2(\hat{q}_\beta)}}\right) \\
&= 1 - \left\{\sum_{k=s}^{n}\binom{n}{k}\left[F_\theta\left(q_\beta - z_{1-\alpha}\sqrt{\frac{\beta(1-\beta)}{nf_{\hat{\theta}}^2(\hat{q}_\beta)}}\right)\right]^k\right. \\
&\left.\left[1 - F_\theta\left(q_\beta - z_{1-\alpha}\sqrt{\frac{\beta(1-\beta)}{nf_{\hat{\theta}}^2(\hat{q}_\beta)}}\right)\right]^{n-k}\right\} \\
&= 1 - [1 - P(Y_U \le s-1)] \\
&= P(Y_U \le s-1),
\end{aligned} \qquad [A.2]$$

where $Y_U$ follows a binomial distribution $B(n, p_U)$ and

$$p_U = F_\theta\left(q_\beta - z_{1-\alpha}\sqrt{\beta(1-\beta)/nf_{\hat{\theta}}^2(\hat{q}_\beta)}\right).$$

Note that there exists an $N$ such that $p_L \approx 1-\beta$ and $p_U \approx \beta$ for $n > N$. In addition, we can write the binomial distribution function as

$$\begin{aligned}
P(W \le k) &= I_{1-p}(n-k, k+1) \\
&\equiv \frac{1}{Beta(n-k, k+1)}\int_0^{1-p} t^{n-k-1}(1-t)^k dt,
\end{aligned}$$

where $W$ follows a binomial distribution $B(n, p)$ and $Beta(a, b) \equiv \Gamma(a)\Gamma(b)/\Gamma(a+b)$ (Wadsworth 1960).

Moreover, by the equation $I_p(a, b) = 1 - I_{1-p}(b, a)$ (Monahan 2011), we can write

$$\begin{aligned}
(A.1) &= 1 - I_{1-P_L}(n-r+1, r) \\
&= I_{P_L}(r, n-r+1) \\
&\approx I_{1-\beta}(r, n-r+1),
\end{aligned}$$

and

$$\begin{aligned}
(A.2) &= P(Y_U \le s-1) \\
&\approx I_{1-\beta}(n-s+1, s),
\end{aligned} \qquad [A.3]$$

when $n > N$.

To prove that [A.1] is greater than or equal to [A.2], we show that either $r + s = n$ or $r + s = n + 1$. Based on the facts

$$\begin{aligned}
\tilde{q}_{1-\beta} &= \inf\{t | F_n(t) \ge 1-\beta\} \\
&= \inf\left\{t \middle| \sum_{i=1}^{n} I(X_i \le t) \ge n - n\beta\right\} \\
&= X_{(r)},
\end{aligned}$$

and

$$\begin{aligned}
\tilde{q}_\beta &= \inf\{t | F_n(t) \ge \beta\} \\
&= \inf\left\{t \middle| \sum_{i=1}^{n} I(X_i \le t) \ge n\beta\right\} \\
&= X_{(s)},
\end{aligned}$$

we have $r = n - n\beta$ and $s = n\beta$ when $n\beta$is an integer. Consequently, we have $r + s = n$.

When $n\beta$ is not an integer, we have $r = [n{-}n\beta] + 1$ and $s = [n\beta] + 1$. As a result, we have $r + s = n + 1$.

Thus, the term $I_{1-\beta}(n - s + 1, s)$ in [A.3] is equal to $I_{1-\beta}(r + 1, n - r)$ when $n\beta$is an integer. Otherwise, it is equal to $I_{1-\beta}(r, n - r + 1)$.

According to Olver et al. (2010), we have

$$I_{1-\beta}(r, n - r + 1) = I_{1-\beta}(r, n - r) + \frac{(1-\beta)^r \beta^{n-r}}{(n-r)Beta(r, n-r)},$$

and

$$I_{1-\beta}(r + 1, n - r) = I_{1-\beta}(r, n - r) - \frac{(1-\beta)^r \beta^{n-r}}{rBeta(r, n-r)}.$$

Therefore, we have $I_{1-\beta}(r, n - r + 1) > I_{1-\beta}(r + 1, n - r)$.

Thus, $P(L_{1-\beta} < q_{1-\beta})$ is greater than or equal to $P(q_\beta < U_\beta)$, when $n$ is large enough.