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A Comparison of Turnaround-Times for Two Popular Specimen Types Used for Newborn Toxicology: Meconium and Umbilical Cord Tissue

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Abstract

Background: Prenatal exposure to illicit substances is responsible for several long-term negative health consequences. It is critical for healthcare professionals to know the extent and scope of prenatal substance exposure in their cases. Several studies exist with mixed results comparing the effectiveness of umbilical cord tissue (UCT) and meconium (MEC) as toxicology specimen types. The specific aim of this study is to compare the use of UCT and MEC regarding the time interval between the birth of the neonate, receipt of the specimen at the laboratory, and the hospital's receipt of the final toxicology report. **Method**: The study queried de-identified results of 5358 consecutive UCT and 706 MEC from our laboratory. **Results**: The mean time from birth to receipt of the specimen at the laboratory for MEC and UCT was 4.5 days ± 2.9 days and 2.8 days ± 1.9 days, respectively. The mean time from birth to final report for MEC was 6.9 days ± 3.8 days, 5.7 days ± 3.3 days, and 8.4 days ± 3.8 days for all MEC specimens, negative MEC, and positive MEC, respectively. The mean time from birth to final report for UCT was 4.3 days ± 2.4 days, 3.5 days ± 2.2 days, and 5.4 days ± 2.2 days for all UCT, negative UCT and positive UCT, respectively. **Discussion/Conclusion**: Receipt of drug test results of the neonate prior to release from the hospital is critical. This study shows that UCT offers an advantage when results are needed quickly to make informed decisions about the health and well-being of newborns.

Keywords

Newborn Toxicology, Prenatal Substance Exposure, Turnaround Time

1. Introduction

Prenatal exposure to illicit substances is responsible for a number of long-term negative health consequences. Healthy People 2030 has declared a goal to increase the number of pregnant persons who abstain from the use of illicit substances from 93% to 95.3% by 2030 [1]. Recent reports indicate that we are still short of that goal [2]. It is critical for healthcare professionals to know the extent and scope of prenatal substance exposure in the cases that come through their practice. Obtaining this knowledge is complicated by the reluctance of maternal self-reporting due to stigma and fear of legal repercussions, therefore, requires the complementary use of objective biomarkers to identify as many cases as possible [3].

This type of testing requires urgency and the careful choice of specimen type for testing. Using a specimen type that is fast and cheap but with low sensitivity may miss identifying cases that need attention. Receipt of the final toxicology report for a test with superior sensitivity after the case has been discharged may interfere with the opportunity to connect the case to much-needed resources. A final decision on testing policy requires a balance of cost, speed, and sensitivity. Several specimen types used for newborn testing have emerged as technology and understanding of newborn toxicology have improved over the decades.

Prior to the development of other specimen types for newborn toxicology, newborn urine was the primary strategy for the detection of prenatal substance exposure. The main advantage of newborn urine testing is that it is inexpensive and may be executed in most hospital laboratories using routine equipment and reagents. However, there are several limitations to relying on newborn urine [4]. Due to the limited detection window and hydration of the neonate, capturing the first void is critical. There is a limited volume of newborn urine, which may result in excessive rejections due to the insufficient quantity of testing. Collection protocols are difficult, and the adhesives on collection bags are irritating to delicate newborn skin.

In the 1980s, MEC became a commonplace alternative to urine as a matrix for newborn toxicology [5]-[8]. MEC, the first fecal matter from the newborn, is a complex and highly variable material [9]. MEC has a long window of detection because it begins to form near the mid-term of the pregnancy and traps analytes and their metabolites. The primary advantages of MEC are the long detection window and a non-invasive collection procedure. The instances of rejection, while not perfect, occurred much less frequently than newborn urine rejections [10]. Limitations include the lack of detection of prenatal exposure in early pregnancy, the heterogeneous distribution of analytes in MEC, and the multistep collection procedure until all the MEC is passed. Additionally, the transition from MEC to milk stool can be difficult to notice. Finally, MEC is a difficult specimen type to work with, and not all laboratories are equipped to execute the analysis appropriately.

Due to the number of limitations to using MEC in an organization's newborn toxicology program, Concheiro and Huestis [10] noted that umbilical cord tissue

(UCT) testing was developed as an alternative specimen type to MEC. Although MEC testing offered an improvement over neonatal urine, insufficient sample volume and subsequent rejections were unacceptable and led to the development of UCT as a specimen type for newborn toxicology testing [11] [12]. There is an abundance of UCT available for each birth, making the collection truly universal. The specimen collection and transfer to the laboratory occurs immediately following birth, which improves turnaround times. Additionally, analytes appear evenly distributed throughout the entire length of the umbilical cord [13]. Umbilical cord collection is a simple single-step procedure, whereas MEC requires multiple collectors making multiple collections over multiple shifts and/or days [11] [12] [14]-[16]. Compared to urine and MEC, UCT contains lower concentrations of substance and the laboratory analysis requires more expensive equipment that can execute testing with higher sensitivity [11] [12] [17].

Several studies have been published that compare the effectiveness of UCT and MEC as newborn toxicology specimen types. The outcomes of these studies have been mixed with specific analytes analyzed, hospital testing selection policies, and laboratory cutoffs being the primary contributors to the differences [18] [19]. Most of these studies mention the availability of UCT immediately following birth as an inherent advantage of UCT over MEC. However, a detailed comparative analysis of turnaround time (TAT) from the time of birth to the time of receipt at the laboratory and the time of birth to final report receipt is currently lacking. The specific aim of this study is to compare the time of birth to the date of receipt into the laboratory and the time of birth to receipt of the final toxicology report for UCT and MEC received at a national reference laboratory.

2. Methods

This retrospective study queried de-identified results from our laboratory information system (USDTL, Des Plaines, IL, USA). Results for 5358 consecutive UCT were retrieved along with 706 MEC from the same period. Secondary analysis of archived de-identified data did not require IRB approval.

All specimens were received at the laboratory using a common commercial courier at ambient temperature. Testing was initiated on the day of receipt. All specimens were submitted to an immunoassay initial test, and presumptive positive results were confirmed using a definitive gas chromatography-mass spectrometry or liquid chromatography-tandem mass spectrometry method.

From the database, we captured the date of birth, date of receipt into the laboratory, and date and time of the release of the final toxicology report. The time from birth to receipt at the laboratory and birth to final report was calculated. The means of these normally distributed unmatched pair turnaround times were compared and evaluated for statistical significance using the unpaired t-test. Additionally, a comparison of the time from birth to release of the final toxicology report for specimens that initially tested negative by immunoassay and those specimens that required further testing was made for each specimen type. Calculations were

performed using Microsoft Excel.

3. Results

During the study period, our laboratory received 706 MEC and 5358 UCT for analysis. The means of the time from birth to receipt of the specimen at the laboratory for MEC and UCT were 4.5 days ± 2.9 days and 2.8 days ± 1.9 days, respectively. The improvement of meantime from birth to receipt of the specimen at the laboratory of UCT over MEC was 1.7 days, and that difference was statistically significant ($p < 0.001$).

The mean of the time from birth to the final toxicology report for MEC was 6.9 days ± 3.8 days. The mean of the time from birth to the final toxicology report for UCT was 4.3 days ± 2.4 days. The birth to final toxicology report TAT improvement of UCT compared to MEC was 2.6 days, and this finding was statistically significant ($p < 0.001$).

For specimens that were reported negative (did not require confirmation testing), the mean time from birth to release of the final toxicology report was 5.7 days ± 3.3 days and 3.5 days ± 2.2 days for MEC and UCT, respectively. We observed an improvement in TAT for UCT of 2.2 days and the difference was statistically significant ($p < 0.001$). For specimens that required confirmation testing, we observed a similar difference. The mean time from birth to release of the final toxicology report was 8.4 days ± 3.8 days for MEC and 5.4 days ± 2.2 days, an improvement of 3.0 days ($p < 0.001$). These results are listed in Table 1 for ease of comparison.

Table 1. Mean number of days from birth to receipt at laboratory and birth to final report for MEC and UCT.

Metric	MEC (days)	UCT (days)	Difference (days)	p-value
Birth to receipt at lab	4.5 ± 2.9	2.8 ± 1.9	1.7	< 0.001
Birth to final report				
All specimens	6.9 ± 3.8	4.3 ± 2.4	2.6	< 0.001
Initial test negative	5.7 ± 3.3	3.5 ± 2.2	2.2	< 0.001
Required confirmation	8.4 ± 3.8	5.4 ± 2.2	3.0	< 0.001

4. Discussion

We have reported here our observations for the mean time from birth to receipt at the laboratory and the mean time of birth to release of final toxicology report for two popular specimen types used for newborn toxicology. We found that in both cases, UCT was on average at least a couple of days faster than using MEC. The time from birth to release of the final toxicology report was further analyzed by comparing all specimens, initial test negative specimens, and specimens that require further testing for confirmation. In all 3, UCT provided the better TAT. Several entries in the literature acknowledge the common sense that UCT results are returned to the hospital quicker than MEC since UCT is available immediately

following birth [19]-[22]. To the best of our knowledge, this is the first report in the literature of a specific comparison of TAT between UCT and MEC used as a specimen type for newborn toxicology.

This data may prove helpful to organizations that are seeking to strike a balance between speed, cost, and sensitivity when making decisions concerning the hospital's newborn toxicology program. Each day of delay in receiving toxicology information promotes missed opportunities and, in some cases, extension of discharge of patients, which unnecessarily increases costs.

This study has several strengths and weaknesses. This study included a large dataset from a national commercial reference laboratory that does business in all 6 US time zones (including Alaska and Hawaii). Analyses were initiated every day that commercial couriers operate, and the analyses were conducted within the same laboratory setting. The generalizability of these findings is limited due to the MEC and UCT not being matched pairs, lack of direct knowledge of the hospital selection policy, lack of direct knowledge of hospital internal workflow, and lack of access to the medical record for the donors of the specimen.

5. Conclusion

Here, we report for the first time a comparison of newborn toxicology testing TAT using MEC and UCT specimen types. UCT outperformed MEC in TAT from birth to receipt at the laboratory and final toxicology report, with a maximum decreased TAT of 3 days in specimens requiring confirmation testing. MEC specimens had greater delays in TAT for receipt of the specimen at the laboratory, highlighting UCT's advantages as a specimen that can be universally collected at the time of birth. This study emphasizes the importance of TAT when selecting the optimal specimen for newborn toxicology testing.

Authors Contribution

The concept of the study was developed by J.J., D.C. and M.J. contributed to the development and review of the manuscript.

Disclosure/Conflict of Interest

The authors are employees of United States Drug Testing Laboratories and the laboratory is in the business of providing the testing discussed in this manuscript.

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Abbreviations

UCT	Umbilical Cord Tissue
MEC	Meconium