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Crib-o-gram infant screening audiometer.

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THE CRIB-O-GRAM INFANT SCREENING AUDIOMETER

by
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programs such as that developed by Downs and Sterritt. Their initial statement in 1970 said that routine mass screening of infants should not be sanctioned except in a research model. In addition, the committee suggested various areas to be studied and indicated that extensive follow-up should be an essential part of the research.

Within a year after the statement by the Joint Committee, Goldstein and Tait published an award winning critique of neonatal screening procedures. They listed and discussed many significant problems with infant hearing screening, but in the final analysis did not recommend its discontinuance. They did suggest that high risk registers should be refined as well as behavioral testing techniques. They felt that hearing evaluations should be performed in well baby clinics, and the awareness of pediatricians to the importance of hearing in early infancy be increased.

Also in 1971, the Conference on Newborn Hearing Screening was held. The discussions of the conference pertained to the pros and cons of neonatal screening, and factors to be aware of when screening. The major recommendations of the conference was for the widespread adoption of a high risk register. The register proposed listed eight factors which dealt with familial history, maternal rubella, structural abnormalities, bilirubin levels, birth weight, and otoscopic findings. The conference did not condone mass behavioral screening but did suggest that some forms of behavioral screening, particularly in conjunction with a high risk register, would be acceptable. To be affective they felt there should be a minimal investment of time, personnel and equipment, and the procedure should detect a significant number of newborns that would be missed by only a high risk register.
The Joint Committee on Infant Hearing met again in 1973 and drafted a supplementary statement which also recommended that infants at risk for hearing impairment be identified by history, then be evaluated and followed-up. The committee remained opposed to routine behavioral screening. The register they adopted was similar to that prescribed by the Conference on Newborn Hearing Screening but was simplified and allowed more latitude in determining risk. The five categories specified at this time are as follows:

I. Family history of hereditary childhood hearing impairment

II. Maternal rubella or other transplacental infections

III. Congenital defects of the ear, nose, or throat. Malformed, low set, or absent pinnae; cleft lip or palate (including sub-mucous cleft); any residual abnormality of the otolaryngeal system

IV. Birth weight less than 1500 grams

V. Any free or indirect serum bilirubin concentration which is judged to be potentially toxic

In terms of follow-up, the Joint Committee recommended that at risk infants receive an audiological evaluation within two months, and that infants with familial history of hearing impairment or history of maternal rubella be given regular hearing examinations to monitor possible progressive losses. It was also suggested that at risk infants who pass the initial testing be screened at a later date by parental questionnaire and an arousal test.

In 1974 and in 1978 two major conferences on the hearing to infants were conducted in Canada.

The major recommendations that came out of the Nova Scotia Conference
on Early Identification of Hearing Loss were that the high risk register of the Joint Committee on Infant Hearing be implemented universally, behavioral screening tests be used supplementally, two year olds be routinely evaluated for communicative function, and that complete assessments of communication skills be required at the entrance to school. Importantly, specific guidelines for behavioral screening were delineated.

The Saskatoon Conference on Early Diagnosis of Hearing Loss dealt primarily with what should be done once a neonate is screened and hearing loss is suspected.

RESEARCH

The research that occurred in the early and mid 1970's was largely directed at screening with behavioral observation audiometry and high risk registers. The results were mixed. Valuable information was obtained for future uses but significant weaknesses became apparent in most models. Ling et al. described the use of behavioral observation audiometry in infant screening as assumption ridden, inefficient, and time consuming. He found a high rate of observer error and was concerned about the affects of early identification upon maternal bonding. Shapiro found excessive false positives and difficulty maintaining adequately trained staff. Using an expanded high risk register, Meyer and Wolf also found an excessive rate of false positives and noted difficulty with follow-up. In a longitudinal study, Feinmesser and Tell also found that an expanded high risk register was too costly and yielded a large number of false positives. They did determine that the restricted register of the Joint Committee would have been practical but at the expense of false negatives.

Interest in traditional neonatal screening continued through the late 1970's primarily through the efforts of audiologists. Otolaryn-
gologists became more reluctant to support neonatal screening programs and pediatricians tended to hold somewhat of a middle ground.\textsuperscript{13}

Besides the push to refine the high risk register and behavioral observation audiology, a significant amount of interest was directed at mechanizing infant hearing screening in the 1970's. Much of this was due to the significant advances in technologies and need to make the process more objective and sensitive. The interest is presently alive, particularly in the area of evoked response audiometry.

Though there was earlier research into the use of respiratory and cardiovascular measures to assess hearing in neonates\textsuperscript{14} neither have been used substantially in a routine screening model\textsuperscript{15}. The semiautomatic movement detection devices such as the crib-o-gram and the accelerometer were among the first mechanized measures developed specifically for that purpose.\textsuperscript{16} The results were positive but Altman et al. (authors of the accelerometer) felt their device was lacking sensitivity.

With the increased popularity, and use of impedance measures and evoked response audiometry, people began assessing these instruments in terms of applicability to the neonatal population, and as useful screening tools. Acoustic reflex testing, which Jerger et al., had proposed as being potentially valuable in assessing neonates did not prove to be as valid as hoped.\textsuperscript{17} Keith, Margolis and Popelka, and Gerber and Cone found that many infants with normal tympanograms did not exhibit reflexes.\textsuperscript{18}

The use of evoked response audiometry, in particular brainstem audiometry, is a recent activity in the area of newborn screening. Most of what has been done has been by Galambos and his associates.\textsuperscript{19} Their
results have been promising but cost, time and administration complexity may make it impractical for routine screening.

THE CRIB-O-GRAM

CONCEPTION AND DEVELOPMENT

The crib-o-gram was developed by F. Blair Simmons in 1969 with the assistance of Frederica Russ and Ronald Strahan. The initial idea to use a motion sensitive transducer was suggested by a student. The investigative program was funded through the Research Grant NS07974-06 of the National Institute of Neurological Diseases and Stroke and by Grant RR-81 of the General Clinical Research Centers Program. The research started in 1970 with preliminary results published in 1974. In the mid 1970's the crib-o-gram project began using field sites to collect additional data and continued to do so until the completion of the investigative program in 1978.

Originally only a multichannel crib-o-gram was used, but because of unique problems faced in intensive care nurseries a portable single channel unit was also developed. The initial instrumentation and data collection was done by John Winstead, Duane Yount, and Joy Nakamura. Bill McFarland became administrator of the program during the final phase of the research. Towards the end of program Telesensory Systems, Inc. of Palo Alto, California became involved in making the single channel crib-o-gram audiometer marketable. This was accomplished by developing the microprocessor, a type of minicomputer.

RATIONALE FOR DEVELOPMENT

The crib-o-gram was devised to circumvent some of the problems which often made traditional behavioral screening impractical. The goal was to develop an automated measure which could reliably, with reduced subjectivity, screen neonates for hearing loss. They wanted
the procedure to require little training, and be inexpensive, easily administered, and simply scored. It was also felt that the tests should be presented at intervals over a period of time, and be independent of nursery routines, random responses, and varying arousal levels.

EQUIPMENT AND PROCEDURE

The following section will describe the original multichannel and single channel crib-o-gram prior to the addition of the microprocessor. The microprocessor will be discussed in the section of present and future uses.

The crib-o-gram consists basically of a motion sensitive transducer, speaker, strip chart recorder with accompanying amplifier, and timing devices. The instrumentation on the multichannel audiometer is much more complex and requires additional components. This unit (the multichannel audiometer) is not commercially available.

![Fig. 1 - The Single Channel Crib-o-gram](image-url)
Transducer

The motion sensitive transducer is a semi-conductor (8101M15 Pixie Transducer, Endevco, Co., Pasadena, California) which was first made for burglar alarm systems. It has a frequency response from DC to over 500 Hz and the sensitivity is such that it must be reduced by bonding it to 0.125 strap steel. After this bonding it is sensitive enough to pick up many of the somatic movements except eye blinks and slight facial grimaces. It is embedded in silicone rubber and, on the multichannel unit, is mounted on the crib frame. With the single channel unit the transducer is connected directly to the recorder by an electrical cord and can be placed within the bassinet or islet. On the single channel unit the sensitivity can also be controlled at the level of the recorder via the gain control setting.

Speakers

The speakers for the multichannel crib-o-gram are mounted in the ceiling of the well baby nursery rooms. They emit a 40 dB 4000 Hz warning tone prior to the stimulus presentation. The warning signal is not used on the single channel unit. The stimulus for both crib-o-grams is a narrow band signal of an approximate width of 2,000 to 4,000 Hz and is 92 dB + 1 dB SPL at the level of the infant's head. Very early in the program the intensity was 85 dB SPL and the signal was a tone which rose rapidly from 2,000 to 4,000 Hz. They found that higher intensity with narrow band noise was more effective. The intensity is low enough to where Simmons reported detecting hearing losses as low as 60 to 65 dB and later McFarland indicated detecting losses of as low as 40 dB.

Strip chart recorder

The recorder is a modified electroencephalograhic type of machine
with the paper chart speed slowed. The multichannel unit recorder was used only at the Stanford Medical Center and is housed several rooms from the well baby nursery, while on the more portable single channel unit, the recorder is placed next to the crib of the infant being screened. The neonate's movements, as well as the presentation of the sound stimulus, and presence of silent trials, are recorded on the chart paper. The multichannel crib-o-gram records the movements of eight babies at one time while the single channel unit records only one.

The graph paper is marked in millimeters. The top line inked on the charts indicates the presentation of the signals and silent test. The central tracing records the movement of the newborn. The portion prior to the signal is the baseline, while that which records the 2.5 seconds following the signal is considered to be the 2.5 second window and is where the responses should occur.

![Diagram of strip chart with sound on, baseline data, and 2.5 second window](image)

Fig. 2 - The Strip Chart
Timing elements

The timing elements control when the sounds are delivered, the duration of each recording, and when silent tests are administered. On the multichannel crib-o-gram a timer also regulates the rotation of test presentations between four groups of eight bassinets so that each infant in tested twenty times within a twenty-four hour period. On the single channel unit the presentation can be as close as one minute apart or separated by as much as 24 hours.

Additional components

With the multichannel unit, the output is coupled to a digitally coded circuit which identifies each bassinet by number so an infant's crib can be plugged into any wall socket connected to the recorder. A switching network is used before the recorder to determine which eight infants are being screened at any one time and which room they are in.

Administration

Single channel crib-o-gram

The infant to be screened is selected and the equipment is moved to the vicinity of the bassinet or isolet. The transducer and speaker and their attached cords are cleaned with alcohol or a cleaning solution. The transducer is placed under the sheet or mattress. At times it may have to be placed directly under the neonate, and if he is on water bags or has special postural supports, several placements may need to be tried before obtaining adequate tracings. Generally it is best to place the transducer under the mid-back region of the infant. The speaker is attached to the foot of the crib. Some clip on while others are on a L shaped stand which is held upright by the mattress.

The equipment is turned on, and the strip chart is attached to the
reel, labeled, and dated. A manual test is run to determine if the gain setting is appropriate for the infant and to give an indication of the adequacy of the transducer placement.

After approximately 10 to 12 hours the machine is turned off manually and the speaker and transducer are removed from the crib. The strip chart is removed and scored. Usually 30 or more tests are administered during this time interval.

Multichannel unit

The multichannel unit is more automatic. All that is needed in the nursery is for the cribs to be plugged into the proper sockets. The information is recorded for up to 32 babies for 24 hours. Most neonates receive 30 or more tests while in the nursery.

Scoring

At first the scoring was quite subjective. A response was considered to be any deviation from the baseline activity with each individual scorer determining whether a deviation was significant. Because of reduced interscorer reliability the scoring system has been gradually refined. During the last three years of the research program a substantially more objective scoring protocol was used. Using the refined system takes approximately ten to fifteen minutes to score a single channel strip chart.

In scoring a test on the strip charts the first step is to determine if the test is scorable. The criteria for this are as follows:

1. The ten second baseline tracing cannot have a difference of over 25 millimeters between its highest and lowest points. 2. The amplitude cannot double within the last three seconds before the onset of the signal. 3. If the baseline tracing is irregular in frequency it cannot
 exceed a variation of 15 millimeters prior to the stimulus.

Once a test is determined as scorable it must be evaluated for a response. Each test is scored by amplitude or frequency based criteria. The most commonly used criteria is the amplitude based which stipulates that in the 2.5 second window following the signal presentation, the amplitude of the largest wave must be at least two times greater than the difference between the highest and lowest points of the baseline tracing. Only those tests whose baseline tracings are rhythmic and regular can be scored according to frequency. To be considered a response the frequency of the tracing in the response window must be 1.5 times greater or lesser than that of the baseline. It is calculated by counting the number of wave cycles in the 10 second baseline tracing and comparing it to the number of cycles in the 2.5 second response window.

Each test is marked either response or no response. Those tests which were silent are later marked and not counted in the number of scorable tests. The total number of scorable tests is tallied and must equal 20 for the screening to be considered valid. The number of responses are tallied and a percentage is calculated. To pass the screening the infant must have responded on at least 10% of the scorable tests.

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Fig. 3 - A Response
Clerical

The following general clerical procedures were used in the cribogram project.

Besides scoring, other paperwork was involved. Identifying information such as birthday, parents, address, and physician was obtained and recorded with the screening results. The results had to be logged in the medical files, and the billing required some additional clerical work.

When an infant failed the screening he was scheduled for a follow-up hearing evaluation with an audiologist when the infant was six months old. Some of the field sites did the follow-up testing when the infants were three months old. The date for the evaluation was sent to the parents and physician when they are informed of the screening failure. They were told what measure was used to screen the infant, what the results were, and that further testing was needed to actually determine if a hearing loss was present. Further letters were sent if the infant did not make the appointment.
When an infant passed the screening the physician was informed at discharge, and the parents were sent a questionnaire when the child was two years old to determine how he was performing communicatively. If the child failed the questionnaire the parents were encouraged to schedule an evaluation with a speech-language pathologist.

RESULTS OF RESEARCH

The majority of the research was performed at the Stanford Medical Center. All of the well babies evaluated were tested with the multi-channel crib-o-gram. Their Intensive Care Unit (ICU) neonates and those tested at the field sites were screened with the single channel crib-o-gram. Eleven field sites were used in the United States and one in Canada.

From 1971 to 1978, 10,497 well babies and 1,576 ICU infants were screened at Stanford. Eleven hearing impaired newborns were identified from the well baby nursery and 28 from the ICU nursery. The false positive rate was 8% for the well babies and 20% for the ICU newborns. The false negative rate was approximately 9% for the well babies and for the ICU nursery it was less than 5%.36

Because much of the early data was suspect due to changes in scoring procedure, kind and intensity of test stimulus, and instrumentation, the later data was also analyzed separately. They found that the sensitivity of the procedure rose significantly particularly with the ICU infants. Of the 1,033 ICU infants screened at this time twenty-two had confirmed hearing losses which is a very high incidence compared to that of the general population. The majority of the hearing losses identified at Stanford were severe or profound, but four were in the 56 to 70 dB range and six were in the 41 to 55 dB range.37

The data obtained from the field sites was inconsistent. The inci-
denoe was not as high as expected at many of the sites.\textsuperscript{38} For example, at the Children's Hospital in Denver only one hearing loss was confirmed out of 622 ICU newborns tested.\textsuperscript{39}

Other information obtained through the course of the research was beneficial to infant screening in general. The periods of the day which were more and least effective to screen newborns was established.\textsuperscript{40} Simmons also found that responses largely occurred within 2.5 seconds of the stimulus onset.\textsuperscript{41} The use of silent tests was not found to be effective statistically.\textsuperscript{42}

The widespread use of the multichannel crib-o-gram was not recommended because of the prohibitive cost and complexity. It was felt that scoring was a major drawback so to make the crib-o-gram more appealing commercially and be more practical a microprocessor was developed which automatically analyzes the results.

The microprocessor, a type of minicomputer, makes the crib-o-gram a more practical tool. It is a small portable component connected to the single channel crib-o-gram and negates the use of the strip chart and automatically adjusts the gain. The data is analyzed automatically according to signal detection theory. After an adequate number of tests are administered it signals whether the neonate has passed or failed the screening. No manual scoring is needed and all tests are valid. The microprocessor was not used in the research project but is a major part of the system being marketed presently.

DISCUSSION

The crib-o-gram seems to do much of what it was designed to do. It is an automated means of screening the hearing of newborns. Some of the positive features are that it takes minimal training to operate, does
not significantly interfere with nursery routines, is reasonably objective, and relatively inexpensive with per infant cost being estimated at approximately $5.00.43

The data for the project was very positive from the Stanford nurseries but that obtained from many of the field sites did not confirm those results. At Stanford the false negative and positive rates were well within an acceptable range, and the incidence of hearing loss was much higher than was previously found.44 The rate was particularly high with the ICU newborns. From this data it would be possible to make a good argument for screening all ICU infants regardless of risk for hearing loss. However using all the field site data makes this conclusion suspect.

One major problem with the crib-o-gram as used in the validation studies was mechanical breakdowns. With the multichannel crib-o-gram there was trouble with cross talk between wires.45 With the single channel unit there was trouble with the inkers, excessive artifacts, shorts between the transducer and recorder, and malfunctioning timing elements.46 Many times the field sites were without their units because of repairs. Another problem was the interference of radio waves. Supposedly these problems have been reduced in the newer commercial models.

The scoring of tracings was cumbersome and time consuming as was the paperwork involved. McFarland considered the set up time reasonable for the single channel crib-o-grams but it's possible that it could be reduced even more if done by the nursing staff.47 Follow-up and the clerical load will remain a problem even though scoring will be eliminated by the utilization of the microprocessor.

From my personal experience with the crib-o-gram at the Denver field site (The Children's Hospital) I did not find the crib-o-gram to be as
sensitive as purported. It did not identify the number of infants it should have comparatively considering the severity of the nursery population. Infants from the ICU nursery who were later identified as being hearing impaired were missed due to invalid strip charts, not being screened, or they had passed the screening. I also find it difficult to accept that moderate hearing losses can be identified with the crib-o-gram.

Mechanical breakdown was a major problem at the Denver field site which considerably reduced my confidence in the system. With the field sites lacking electronic maintenance people such as those used at Stanford it was difficult to provide a consistent screening program. This may also relate to the disparity between the Stanford data and the results reported by the field sites.

Another concern was the number of infants who were followed up less intensively when they had invalid strip charts. When a neonate had an invalid strip chart a second screening could not always be performed. The parents were encouraged to bring the infant back for testing but little else was done for follow-up.

PRESENT AND FUTURE USES

The addition of the microprocessor on the commercial units makes the crib-o-gram more practical. It was first thought that the microprocessor would be able to determine when a neonate's arousal level was such that it would be more likely to respond but that is not the case. The arousal levels could not be effectively predicted from the baseline activity but is able to prevent the completion of a test if the activity is excessive. The single channel crib-o-gram may prove to be an effective and practical tool for ICU nurseries and for well babies at risk for hearing
loss. To use it for mass screening is considered to be too costly and time consuming.

In the future it may be useful in screening infants for central hearing disorders. Mencher found that these types of children had abnormal response patterns which may show up on a tracing where time and amplitude can be evaluated.\(^49\) Mencher also found that infants passing the crib-o-gram who were later diagnosed as perceptually disordered tended to have lower scores than normal infants.\(^50\)

Additional research using the microprocessor is needed.

SUMMARY

The crib-o-gram is a semi-automatic system to behaviorally screen hearing in infancy by recording movement responses to sound. At the Stanford Medical Center it was found to be effective particularly with ICU infants but the data from the field sites did not confirm those results. The lack of equipment maintenance at the field sites may have been a significant factor in reducing their incidence rate since mechanical breakdown was a major problem.

Other problems such as scoring and invalid tests were found with the crib-o-gram research prototypes but are not factors with the commercial single channel crib-o-gram unit. This is due to the addition of a microprocessor. The multichannel crib-o-gram was not considered practical for commercial use, and because of cost the single channel unit was only recommended for ICU infants and those at risk for hearing loss.

A longitudinal study of the effectiveness of the commercial crib-o-gram with the microprocessor was not performed but would be useful in determining its actual effectiveness.
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