Aust N Z J Obstet Gynaecol 2023; 63: 535–540

ANZJOG

DOI: 10.1111/ajo.13681

ORIGINAL ARTICLE

Validation of a tool for determining the clinical utility of stillbirth investigations

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Conflict of Interest: The authors report no conflicts of interest.

Received: 25 February 2022;
Accepted: 25 March 2023

Background: Up to 20% of all stillbirths and 45% of term stillbirths are currently classified as unexplained. Many of these stillbirths do not undergo currently recommended investigations. This may leave questions unanswered and not identify stillbirths with a recurrence risk in subsequent pregnancies.

Aims: To validate a new tool (Stillbirth Investigation Utility Tool) to identify the clinical utility of investigations in stillbirth and the inter-rater agreement on cause of stillbirth using the Perinatal Society of Australia and New Zealand-Perinatal Death Classification (PSANZ-PDC).

Materials and methods: Thirty-four stillbirths were randomly selected for inclusion, each assessed independently by five blinded assessors. The investigations were grouped into three categories: clinical and laboratory; placental pathology; and autopsy examination. The cause of death was assigned at the end of each group. Outcome measures were clinical utility of investigations measured by assessor rated usefulness and inter-rater agreement on the assigned cause of death.

Results: Comprehensive maternal history, maternal full blood count, maternal blood group and screen and placenta histopathology were useful in all cases. Clinical photographs were not performed and should have been performed in 50% of cases. The inter-rater agreement on cause of death assigned after all investigation results was 0.93 (95% CI 0.87–1.0).

Conclusions: The new Stillbirth Investigation Utility Tool showed very good agreement in assigning the cause of death using PSANZ-PDC. Four investigations were useful in all cases. Minor refinements will be made based on feedback to enhance usability for wider implementation in research studies to assess the yield of investigations in stillbirths.

KEYWORDS

autopsy, clinical utility, death classification, investigations, placenta, stillbirth, yield

INTRODUCTION

Australia is one of the safest places in the world for pregnancy and childbirth, yet the national rate of stillbirth remains higher than other high-income countries and continues to affect more than 2000 families each year.[1,2] In Australia in 2019 there were 2183 stillbirths representing an overall rate of seven stillbirths per 1000 live births.[3] This rate has remained largely unchanged over the past two decades, although a reduction has been shown in stillbirths of 28 weeks or more gestation.[3,4]

Stillbirths place a heavy psychosocial and economic burden on families, and health systems.[5] It is important to understand the causes of stillbirth, for families to know why their baby died, to inform clinical care in subsequent pregnancies and to develop prevention strategies to decrease the stillbirth rate.[5] In Australia, up to 20% of stillbirths, including 45% of term stillbirths are classified as unexplained.[2] Failure to identify the cause can be distressing to families and clinicians.[5] The variation in unexplained stillbirths suggests misclassification which is likely to be due to inadequate investigation and approaches to classification.[5,6] Factors contributing to suboptimal investigation include lack of clinician awareness of investigations, lack of evidence-based stillbirth protocol, recommended tests being unavailable, and concerns from the family.[5-7] Not all investigations are funded meaning that families or health services may be out of pocket for investigations performed.[8] Some services may not offer the full suite of investigations as it may not be financially viable for them to do so.[8] Increasing the education and training of healthcare professionals has been recommended to improve investigation of stillbirths.[9,10]

In 2004, the Perinatal Society of Australia and New Zealand (PSANZ) released the first edition of Clinical Practice Guideline (CPG) for perinatal mortality, to enhance a systematic approach to care across Australia and New Zealand including investigations and classification of stillbirths.[11] Subsequent editions continue to align best practice with clinical research, the latest in 2018. The recommended core investigations have reduced from 23 in 2012 to eight in 2016.[11,12] Further selective or sequential investigations could be carried out based on information revealed from the core investigations, or in the presence of specific clinical scenarios.[11]

Previous studies have examined the clinical utility of stillbirth investigations.[13,14] Drawing on these previous studies to apply in an Australian setting, we designed a new tool, called the Stillbirth Investigation Utility Tool to determine the clinical utility of investigations and agreement in assigning cause of stillbirth. The aim of this study was to validate this tool to determine if it was fit for purpose before wider use in an Australian setting.

MATERIALS AND METHODS

Development of the tool

The Stillbirth Investigation Utility Tool was based on previous studies and refined through consensus and pilot testing among the investigators.[13,14] Modifications were made to incorporate an option if the investigation was not performed and to include the list of recommended investigations derived from the PSANZ PM CPG (2009) (Appendix S1).[12,15]

Study sample

A random selection of 34 cases was included in this validation study. These cases formed 5% of the 697 cases of the Stillbirth Causes Study, a large multi-centre, prospective cohort study over 2013–2018 across 18 maternity hospitals providing maternity services across Australia to identify an optimal investigation protocol for stillbirths. Stillbirths at ≥20 weeks gestation and/or ≥400 g birthweight were eligible for inclusion, while terminations were excluded.

Outcome measures

- Clinical utility of the investigations performed as defined by usefulness in contributing to identification of the cause of death.
- Inter-rater reliability for assigning cause of death using the PSANZ-PDC.
- Change in cause of death, from laboratory and clinical investigations, to after the placenta and autopsy results were evaluated.

Case review procedure

The panel of assessors were identified by seeking an expression of interest through the investigators of the Stillbirth Causes study. Five assessors made up the panel including: pathologist, pathology registrar, maternal-fetal medicine specialist, obstetrics and gynaecology registrar, and hospital medical officer. The five assessors undertook initial training on the use of the tool in individual meetings with the lead investigator.

An individual case summary was compiled extracting data from the main study data set and provided to each panel member. Each stillbirth was assessed independently by the five assessors to determine the clinical utility of each investigation and the cause of death, blinded to the cause of death previously assigned by the participating hospitals. Clinical utility was defined by usefulness of the investigation in contributing to identification of the cause of death and, for each investigation, was assigned to one of six categories. The term 'useful' was defined as being practically applicable to confirm or exclude cause of death. For example, maternal full blood count can identify a high white cell count, which can corroborate ascending amniotic infection as a cause of death. When an investigation was performed it was categorised as: useful-assigned cause of death; partially useful-confirmed cause of death; partially useful-excluded cause of death; and not useful. When an investigation was not performed it was categorised as: not performed-should have been performed; and not performed-not necessary.

A stepwise approach was used assigning cause of death across three groups of tests: Group 1 – clinical and laboratory investigations; Group 2 – placental pathology; and Group 3 – autopsy examination.[14] At the end of each group the main classification for cause of death was recorded. The list of investigations in each group is shown in Table 1.

Any case that showed discordance between the reviewers was reviewed again by all reviewers and discussed to determine consensus.

The ease of use of the tool was assessed through a post-study discussion between the lead investigator and each assessor with open text questions.

Data collection and analysis

For the cohort study, participating hospitals were asked to investigate, review, and classify the cause of death for all stillbirths according to the PSANZ PM CPG (2009) and enter study data into a purpose-built application.[12,15] Data included demographic characteristics, pregnancy outcomes, investigations undertaken, and cause of stillbirth.

Following review by panel members data for the validation study were entered into a purpose-built database.[16]

Data analysis was undertaken using R Statistical computing software.[17] A Gwet agreement coefficient 1 (Gwet AC1) statistical analysis was performed instead of Cohen's kappa as studies have identified a paradox when high actual agreement can be associated with a low kappa.[18,19] The Gwet AC1 statistics were calculated for assigning cause of death.[20] The GwetAC1 was rated as poor (<0.20), fair (0.21–0.40), moderate (0.41–0.60), good (0.61–0.80) and very good (0.81–1.00).[21] Descriptive statistics of the clinical utility of the investigation were performed.

Details of ethics approval and consent

This study was approved by the Mater Health Services Human Research Ethics Committee (HREC) on 20 December 2011 (reference no.: HREC/1745M), Queensland Health/Royal Brisbane & Women's Hospital on 17 December 2012 (reference no.: HREC/12/QRBW/284), ACT Health HREC on 5 November 2012 (reference no.: ETH.10.12.220), Northern Sydney Local Health District HREC on 31 January 2013 (reference no.: 1212-411M), HREC of Northern Territory Department of Health and Menzies School of Health Research (reference no.: HOMER-2012-1876), Aboriginal Health Research Ethics Committee of South Australia on 5 November 2012 (reference no.: 04-12-480), Women's & Children's Hospital Network (WCHN) HREC on 5 December 2012 (reference no.: HREC/12/WCHN/69), University of Tasmania HREC Tasmania Network on 30 November 2012 (reference no.: H0012864), Mercy Health HREC (Victoria) on 11 June 2013 (reference no.: R13/07) and Western Australia Aboriginal Health Ethics Committee on 19 November 2012 (reference no.: 447). Due to delays and complications during the HREC review process,

TABLE 1 List and proportion of investigations performed according to group

Group	Investigation	*n* (%) test performed
Group 1 – clinical and laboratory investigations	Comprehensive maternal medical and pregnancy history	34 (100)
	Ultrasound scan for fetal abnormalities	17 (50)
	Ultrasound scan for amniotic fluid assessment	10 (29)
	Amniocentesis for infection	8 (3)
	Amniocentesis for cytogenetics	5 (15)
	Low vaginal/peri-anal swab	16 (47)
	Full blood count (Hb, white cell count, platelets)	34 (100)
	Blood group and antibody screen	34 (100)
	Maternal-fetal haemorrhage	28 (82)
	Renal function tests (creatinine, urea)	27 (79)
	Urate	22 (65)
	Liver function tests	27 (79)
	HbA1c	24 (71)
	Thyroid function test	11 (33)
	Bile acids (fasting and/or non-fasting)	10 (29)
	Cytomegalovirus	26 (76)
	Toxoplasma	25 (74)
	Parvovirus B19	23 (68)
	Rubella	26 (76)
	Syphilis	26 (76)
	Anticardiolipin antibodies	23 (68)
	Lupus anticoagulant	22 (64)
	Anti-protein C resistance	18 (53)
	Thrombophilia testing at follow-up visit	9 (26)
	Fasting homocysteine	2 (6)
	Protein C deficiency	7 (21)
	Protein S deficiency	8 (24)
	Anti-thrombin III	4 (12)
	Prothrombin G20210A mutation	6 (18)
	Factor V Leiden mutation	4 (12)
	MTHFR 3 mutation	1 (3)
	Clinical photographs taken	12 (35)
	Swabs of ear and throat	17 (50)

(Continues)

TABLE 1 (Continued)

Group	Investigation	*n* (%) test performed
	Babygram	4 (12)
	Full blood count with smear	1 (3)
	Chromosomal analysis from the baby – tissue or blood (taken by clinician)	2 (6)
	Newborn Screening Test	1 (3)
	Placental swabs for microbiology by clinician	17 (50)
	Biopsy for cytogenetics taken by clinician	4 (12)
Group 2 – placental pathology	Placental histopathology	34 (100)
	Placental swab for culture taken by pathologist	22 (65)
	Other site culture taken by pathologist	0
	Tissue for chromosomal analysis taken by pathologist	16 (47)
	External examination by expert in addition to clinician at the birth	2 (6)
	Clinician macroscopic examination of placenta and cord	4 (12)
Group 3 – autopsy examination	Magnetic resonance imaging	3 (9)
	Needle biopsy	0
	Laparoscopic	0
	Post mortem ultrasound scan (following birth)	0
	Autopsy – full	19 (56)
	Autopsy – partial	3 (9)

no stillbirths were recruited from health facilities in Western Australia. The approved study is classified as low-negligible risk to participants. All parents of study participants provided consent at the hospital level for any investigations completed. Due to the level of data sensitivity (non-identifiable), a waiver of consent was requested and approved to collect and analyse data for the purpose of this study.

RESULTS

Among the stillbirths included in the validation study, 18/34 stillbirths (53%) were less than 27 weeks gestation and 6/34 (18%) stillbirths were at term, with 28/34 (82%) antepartum deaths. Maternal characteristics are shown in Table 2.

TABLE 2 Selected maternal demographic characteristics for mothers and stillbirth (*n* = 34)

	Stillbirths, *n* (%)
Ethnicity	
Aboriginal or Torres Strait Islander	4 (12)
Sub-Saharan African	2 (6)
South Asian	2 (6)
Caucasian	16 (47)
Other or not stated	10 (29)
Age (years)	
<20	1 (3)
20–34	20 (59)
≥35	13 (38)
Parity	
Nulliparous	15 (44)
Primiparous	14 (41)
Multiparous (≥3)	5 (15)
Previous stillbirth	2 (6)
Pregnancy	
Multiple pregnancy (births)	2 (6)
Singleton	32 (94)
Timing of birth	
Intrapartum	3 (9)
Antepartum	28 (82)
Unknown	3 (9)
Gestational age	
<27	18 (53)
28–36	10 (29)
≥37	6 (18)

Clinical utility of investigations for stillbirth

The frequency of the investigation performed ranged from 0% to 100% (Table 1). No case had all recommended investigations performed. At least four investigations were performed in every case. Twenty-two investigations were performed in more than 50% of cases.

Preliminary findings of the clinical utility of investigations for the 34 included stillbirths is summarised here. Four investigations were not performed in any case and the assessors identified they were not necessary for three investigations (needle biopsy, laparoscopy and post mortem ultrasound following birth). Of the investigations not performed, the five assessors considered that clinical photographs should have been performed in 50% of cases.

A comprehensive maternal history, maternal full blood count, maternal blood group and screen and placenta histopathology were assessed by all five assessors as useful or partially useful in all 34 cases. Microbiological investigations of mother were found to be useful or partially useful by all five assessors in 75% (25/34)

cases. This included tests for toxoplasmosis, rubella, cytomegalovirus (CMV) and syphilis. Parvovirus investigation of mother, antenatal ultrasound, placental microbiology (by either the clinician or pathologist) and full autopsy were useful or partially useful by all five assessors in 50% (17/34) of cases. No investigation that was performed was identified as 'not useful' by all five assessors in 100% of cases.

Agreement with causes of stillbirth

The study protocol allowed for one cause of death to be recorded. The agreement was calculated for the final assessor-assigned cause of death.

The inter-rater agreement, measured by Gwet AC1 on cause of death assigned after all investigation results were reviewed was 0.93 (95% CI 0.87–1.0) (Table 3).[21]

Change in cause of death

The PSANZ-PDC was recorded for each stillbirth after each investigation group. The cause of death changed after Group 2 investigations were reviewed, primarily due to the placental report findings in 12 (35%) cases. In the 12 cases, the cause of death was spontaneous preterm birth with chorioamnionitis (PSANZ-PDC 10.11), unexplained antepartum fetal death with full investigations (PSANZ-PDC 11.1) and perinatal bacterial infection (PSANZ-PDC 2.1). The cause of death did not change after the addition of the autopsy (full or partial) results for any of the included stillbirths.

Ease of use of tool

The assessors found the tool easy to use and identified two components that required further changes: removal of term 'partially useful' and addition of up to three associated causes of death to be in line with current practice (four in total).

DISCUSSION

Main findings

This is the first study to validate a stillbirth investigation utility tool. Despite recommended investigation protocols, none of the stillbirths in this study had all recommended investigations performed.[7] Four investigations were performed in all cases and identified as useful by all five assessors. They were a comprehensive maternal history, maternal full blood count, maternal blood group and screen and placenta histopathology. Three investigations were not performed in any case (needle biopsy of baby organs, laparoscopy of the baby and post mortem ultrasound following birth of the baby) as these approaches to investigation of stillbirths are not routinely used in Australia.[7] While these techniques are yet to be included in routine practice, international studies have shown the benefit of a minimally invasive autopsy utilising investigations such as laparoscopy and needle biopsies where permission for a full invasive autopsy has not been granted.[22-24]

TABLE 3 Gwet AC1 statistic for cause of stillbirth after each group of investigations

Group of investigation	Gwet AC1 (95% CI)
Group 1 – clinical and laboratory investigations	0.91 (0.85–0.99)
Group 2 – placental pathology	0.95 (0.89–1.00)
Group 3 – autopsy examination	0.93 (0.87–1.00)

CI, confidence interval.

In the two previously reported studies, 100% compliance with the recommended stillbirth investigation protocol was recorded.[13,14] This study utilised a subset of stillbirths from a larger cohort study reported by Sexton *et al*.[7] showing a 70% or more compliance for nine of the 51 investigations: comprehensive history (82%), maternal full blood count (94%), cytomegalovirus (CMV) (71%), toxoplasmosis (70%), renal function tests (75%), liver function tests (LFT) (79%), external examination by paediatrician (86%), and placental histopathology (92%).[7]

The tool's inter-rater reliability of 0.93 among five assessors showed very good reliability in recording the cause of death. The assessors ranged in clinical experience from a junior medical officer to a senior consultant. The robustness is an important feature of any tool. For example, Flenady *et al*.[25] assessed six classification of stillbirth systems by nine teams from seven countries. They found the inter-rater agreement to range from poor to good depending on the classification system applied. While the classification systems were found to be easy to use, the amount of information captured by the systems and the variable agreement meant that no system could be recommended for universal use. When any tool is implemented, it is important to have good to excellent agreement to ensure there is consistency among multiple users and across multiple sites.

The assessors found the tool easy to use. They identified two components that required a change. The terminology of partially useful was found to be confusing and the assessors preferred the term useful or not useful. The tool will be modified to remove the term partially useful and to add categories of 'useful-confirmed cause of death' and 'useful-excluded cause of death'. In this study, a single cause of death using the PSANZ-PDC was recorded. It was agreed that this is not reflective of current practice where up to three associated conditions can be recorded. Therefore, the tool will be modified to incorporate up to three associated causes of death.

Strengths and limitations

This is the first study to validate a tool to examine the clinical utility of stillbirth investigations using a panel with a range of clinical experiences from a consultant to a medical officer. The stillbirths reviewed were randomly selected from a consecutive series of

stillbirths occurring at 18 maternity hospitals across seven states and territories in Australia.

A limitation is no case had every investigation performed. The study protocol allowed for the clinician lead to upload the results into the purpose-built database. There were many investigations where no data were uploaded, and it was assumed the investigation was not performed.

The Stillbirth Investigation Utility Tool was very good in assigning cause of death using PSANZ-PDC. Four investigations were useful in every case. The tool showed very good agreement across a panel of assessors in cause of death assignment. The tool was found to be easy to use. Minor refinements will be made to enhance usability for wider implementation in research studies to assess the yield of investigations in stillbirths.

ACKNOWLEDGEMENTS

This study is supported under National Health and Medical Research Council Grant #1029613 'Investigating Causes of Stillbirths: A Prospective Cohort Study Examining Use and Effectiveness of a Comprehensive Investigation' and the Stillbirth Centre for Research Excellence. The authors have declared no conflict of interest for this research from any funding agency in the public, commercial, or not-for-profit sectors. Open access publishing facilitated by The University of Queensland, as part of the Wiley - The University of Queensland agreement via the Council of Australian University Librarians.

AUTHOR CONTRIBUTION

VF conceived and designed the study with DE, MC, TYK. TM led the development of the tool, the data collection, management and analysis with support from VF, JD, TYK, MC, DE. AM, SP, CO, FC, SM reviewed the cases. TM drafted the manuscript. MC provided statistical support. All authors reviewed and commented on manuscript drafts and approved the final version for submission.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Appendix S1. Stillbirth investigation utility tool.