

ORIGINAL RESEARCH

Urinary alcohol and ethyl glucuronide as a screening tool for alcohol use in pregnancy: A multicenter prospective study

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Abstract

Introduction: Reports indicate that up to 60% of pregnant women in Ireland consume alcohol and Ireland may have the third highest prevalence of fetal alcohol syndrome in the world. We sought objective evidence of alcohol intake and the acceptability of urinary alcohol screening.

Material and Methods: This was a multicenter, prospective study conducted at one urban and two semirural maternity units. Pregnant women at their first visit (~13 weeks gestation) were invited to participate. Urinary samples were obtained with individual consent. Samples were anonymized and tested for alcohol and ethyl glucuronide at a central laboratory. The rate of sample positivity for ethanol (at a cut-off of 30 mg/dL) and ethyl glucuronide (at a cut-off of 500 ng/mL) was reported. The percentage of women consenting to testing was recorded. Results were compared with previous questionnaire or interview-based studies.

Results: One thousand fifty-three urine samples were analyzed. None tested positive for ethanol but 4/1053 (0.38%) contained ethyl glucuronide. Three samples were positive in the urban cohort, 3/730 (0.41%) and 1/323 (0.31%) in the semirural centers. Consent was obtained in 96% and 98% in two semirural centers compared to 78% in the urban center (565/722 vs. 323/336. $p < 0.01$). Acceptability in the urban center depended on who requested consent and varied between 65% and 100% ($p < 0.01$). Consent to participate was significantly higher and detected alcohol use was significantly lower than in previous, interview or questionnaire-based studies.

Conclusions: Alcohol intake appears to be much less common than previously estimated. The consent rates for urinary alcohol testing are high and are influenced by who is requesting consent.

KEYWORDS

alcohol, ethyl glucuronide, fetal alcohol syndrome, pregnancy, screening

Abbreviations: EtG, ethyl glucuronide; FASD, fetal alcohol spectrum disorder.

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1 | INTRODUCTION

Fetal alcohol spectrum disorder (FASD) is a leading cause of potentially preventable neurodevelopmental disability globally.¹ The estimated prevalence exceeds 1% of the general population in 76 countries.² It has been reported that alcohol use is very common in pregnant females in Ireland at 60.4% (95% CI 42.8–76.8), which is one of the highest rates in the world.³ As a result it is estimated that Ireland has the third highest prevalence of fetal alcohol spectrum disorder (FASD) at 47.5 per 1000 population.² This is only exceeded by South Africa at 111/1000 and Croatia at 53.3/1000. The figure of 60% alcohol use in pregnancy is based on the SCOPE study which employed a structured questionnaire in nulliparous women at 15 weeks gestation.^{4,5} Approximately 15% reported at least 2 episodes of binge drinking during pregnancy. Other studies in Ireland, using similar methodology, have reported alcohol intake rates between 19.4% and 53%.^{6–9} Alcohol use in pregnancy is therefore challenging to reliably quantify, and studies to date have largely depended on women's self-reported drinking practices. The variability in questionnaire results raises the possibility of inaccuracy in recall and self-reporting of alcohol intake. The aim of this study was to prospectively investigate objective measures of alcohol intake in this population.

2 | MATERIAL AND METHODS

This was a multicenter, prospective study with institutional ethics approval and maternal written consent.

Pregnant women attending their first booking visit, at approximately 13 weeks gestation, undergo routine urinalysis for glucose and infection. Urine samples from participants were collected after routine testing was performed and prior to discard. The urine samples were transferred to the toxicology laboratory in the National Drug Treatment Centre within 24 h. Samples were tested on the day of receipt or kept refrigerated and tested the following day if received late in the day. Each sample was tested for ethanol and ethyl glucuronide (EtG), but also tested for creatinine to ensure the sample qualified as urine and was not substituted for another substance. Screening for alcohol use in pregnancy continued during the study period as per local guidelines. There was no change to routine antenatal care.

All women over the age of 18 were eligible for inclusion in the study. Consent for anonymous testing for ethanol and EtG was obtained from a member of the research team. In the two semirural units, consent was obtained from a research nurse. Consent was obtained by clinic staff (healthcare assistant, midwife, doctor) in the urban center. All staff obtaining consent were briefed on the research project. No scripted consent template was used.

Ethanol was tested using the DRI® Ethyl Alcohol Assay (Thermo Scientific Inc. Mass., USA). The DRI Ethyl Alcohol Assay is a liquid, ready-to-use, kinetic method based on the high specificity of alcohol dehydrogenase (ADH) for ethyl alcohol. In the presence

Key Message

Alcohol consumption during pregnancy in Ireland may not be as common as previously believed. Urinary alcohol screening may be a useful adjunct to current antenatal screening.

of ADH and nicotinamide adenine dinucleotide (NAD), ethyl alcohol is readily oxidized to acetaldehyde and NADH. The enzymatic reaction can be monitored spectrophotometrically at 340 nm. The National Drug Treatment Centre laboratory employs a cut-off of 30 mg/dL (also known as mg%) that is, urine samples with ethanol concentrations under 30 mg/dL are reported as negative. Results of 30 mg/dL or higher are reported as a quantitative result, for example, 46 mg/dL.

Ethyl glucuronide was detected using the DRI® Ethyl Glucuronide assay (Thermo Scientific Inc. Mass., USA) at a cut-off of 500 ng/mL. This enzyme immunoassay uses specific antibodies that can detect ethyl glucuronide without any significant cross-reactivity to other glucuronide compounds. EtG can be detected in urine for up to 24 h after ingestion of small quantities of alcohol and up to 130 h after excessive consumption.^{10,11} Sensitivity of up to 100% has been described but false negatives can occur with the ingestion of small quantities of alcohol or a significant interval between alcohol intake and sample collection.¹² EtG is very specific for the detection of alcohol. Exposure to other forms of alcohol, for example, propyl alcohol-based hand sanitizer, could result in false positive results in urine, but is very unlikely in the context of an antenatal clinic.¹³

This study was approved by the ethics committee of the National Maternity Hospital, Dublin and the HSE South Eastern Area Research Ethics Committee. Differences between groups were evaluated using the Chi-square (and Fisher's exact) test using the Prism 10 statistical program (GraphPad Software Inc., California, USA).

3 | RESULTS

A total of 1066 individuals consented to inclusion in the study. Thirteen samples contained insufficient urine and 1053 were analyzed. The results are summarized in Table 1. The urban center provided 730 samples and the two semirural centers, 270 and 53 samples each. Subjects in the urban center were significantly older than in the semirural centers (mean age 33.6 ± 0.2 SEM years vs. 30.3 ± 0.3 years $p < 0.01$).

Consent was obtained in 323/335 (96%) of women approached by two research nurses in the two semirural centers. Information on the numbers approached was available on a proportion of women in the major urban center. Of these, 565/722 (78%) agreed to participate ($p < 0.01$ compared to semirural centers). Participation

TABLE 1 Results.

	Center 1 (Urban)	Center 2 + 3 (Semi-Rural)	p value
Samples collected	730	323	
% of total samples	69%	31%	
Mean age (+SEM)	33.6±0.17	30.3±0.27	p<0.01
Age range	19–47	20–48	
Ethanol positive samples	0	0	
% Ethanol positive samples	0	0	
EtG positive samples	3	1	
% EtG positive samples	0.41	0.31	

depended on who sought consent. It was 100% for a doctor ($n=32$), 94% for a midwife ($n=34$), 97% for one particular health-care assistant ($n=128$), and between 65% and 81% for three other health-care assistants ($n=528$) ($p<0.01$).

None of the samples tested contained ethanol but 4/1053 (0.38%) tested positive for ethyl glucuronide. Three samples were positive in the urban 3/730 (0.41%) and 1/323 (0.31%) in the semirural centers.

Samples were tested for creatinine to confirm the presence of urine. Approximately 10% of samples were classified as dilute (creatinine 2–20 ng/mL) with the remaining samples all containing >20 ng/mL (i.e. normal). No samples were negative for creatinine.

4 | DISCUSSION

This is the first study in Ireland to report the use of objective, laboratory methods to detect alcohol use in early pregnancy. The main finding was the low number of antenatal samples containing ethanol or EtG. This was surprising, given the result of previous retrospective interview and questionnaire-based studies as discussed below. However, discordance between self-reported alcohol use and EtG results has been noted in other contexts,¹⁴ usually in individuals who deny alcohol use having positive tests.

Results of previous studies on alcohol intake in pregnancy in Ireland are summarized in Table 2. All used interviews or questionnaires. The proportion of women consuming any alcohol in pregnancy varied from 19.4% to 60%, while alcohol use in the first trimester varied between 1% and 60%. Heavy or binge drinking during pregnancy ranged from <1% to 23%. Participation rates in these studies ranged from 55% to 78%. Participation rates in the two largest studies were significantly lower than in our current study (5690/8531 and 7237/11134 vs. 888/1107 $p<0.01$). Part of the discrepancy between our results and these studies may be due to the fact that alcohol use appears to be frequent between the time of conception and recognition of pregnancy.¹⁵ Studies including alcohol intake in this window period are likely to report

higher rates. However once pregnancy is recognized the majority of women appear to stop or moderate their alcohol intake.¹⁵

Previous objective studies have reported similar findings. Comasco et al.¹⁶ examined alcohol use before and during pregnancy and found that 89% of women reported consuming alcohol prior to pregnancy, whereas only 12% reported drinking during pregnancy. Objective biomarker measurements (carbohydrate-deficient transferrin and phosphatidylethanol) did not indicate significant alcohol exposure in any of the pregnancies. Consistent with our findings, this study supports the conclusion that most women substantially reduce their alcohol intake during pregnancy and that high levels of prenatal alcohol exposure may be less prevalent than suggested in earlier studies, such as Popova et al.²

Another possibility is that societal changes have resulted in lower alcohol use among reproductive age women in Ireland than before. In Ireland, alcohol consumption per capita has decreased from 14 liters per year in 2003 to 10 liters per year in 2022.¹⁷ This may be because of effective public health messaging or perhaps alcohol is being superseded by other forms of substance use. An Italian study in 2023 also demonstrated low alcohol consumption during pregnancy. In this multicenter study, hair analysis of EtG demonstrated an abstinence rate of 94% and meconium samples were negative in >99% of cases.¹⁸

The second significant finding was the high acceptability of urine alcohol testing in this group of pregnant women. The participation rate was significantly higher than in previous studies. Interestingly, the participation rate appeared to depend on the enthusiasm and motivation of the individual seeking consent. This suggests it may be a valuable and acceptable adjunct to history taking in the antenatal clinic. Given that the samples in this study were anonymized, an opt-out facility for individuals who would prefer not to have their urine tested may result in high rates of participation. In theory, a cohort of women consenting to urinary alcohol testing, such as the group in this study, are likely to exhibit similarly low levels of EtG positivity. It may be possible to design interventions to focus on the group of women who decline testing in an effort to target those likely to be at highest risk.

A key strength of this study is its prospective design and the objective measurement of alcohol intake. The participation rate was high compared with previous studies. The study included urban and semirural communities and is thus probably representative of the population as a whole. A number of studies report data on hair and meconium alcohol testing. The ultimate goal of research in this area is to reduce FASD. We therefore propose that biomarkers that predict current use are potentially more clinically useful than retrospective identification of pregnancies at risk.

A number of limitations exist in this study. EtG detects light drinking for 2 days and heavy drinking up to 5 days prior to the test.¹⁰ It is not a marker of longer-term alcohol use. Ideally, we would use the Phosphatidylethanol (PEth) test, but this requires a specific blood sample and is significantly more expensive. A variety of cut offs have been used in previous studies. 30 mg/dL and 500 ng/mL were selected in this study to reflect clinically

TABLE 2 Studies on maternal alcohol intake in pregnancy in Ireland.

References	Type of study	Proportion participating	Alcohol intake during pregnancy	Binge, heavy or frequent drinking during pregnancy	Alcohol consumption in the 1st trimester
SCOPE study 2013 ⁴	Prospective cohort study Interview (1st trimester only)	5690/8531 (67%)	60%	23%	60%
Urban maternity hospital 2013 ⁶	Prospective cohort study Interview	907/1662 (55%)	32%	<1%	1%
GUI study 2014 ⁷	Retrospective- infants 9 months old Computer-assisted personal interview	7237/11 134 (65%)	19.4%	1%	9.7%
Primary care 2014 ⁸	Prospective questionnaire (+phone interviews)	78% for one sub-group (C)	37.6%	2.5%	n/a
PRAMS study 2013 ⁹	Retrospective questionnaire	82/124 (66%)	53%	n/a	28%
Current study	Prospective urinary alcohol and EtG Semirural	323/335 (96%)	<1%	n/a	<1%
Current study	Prospective urinary alcohol and EtG Urban	565/722 (78%) ^a	<1%	n/a	<1%

Abbreviation: EtG, ethyl glucuronide.

^aInformation available for 565/730 samples analyzed.

significant alcohol exposure. International guidelines such as FASD Canada¹⁹ describe a threshold of neurodevelopmental effects as consumption of 7 standard units per week or 4 or more units on a single occasion.

Despite a high acceptance rate in our study, it was not 100%. It is possible that individuals who regularly consume alcohol may not have consented and the study may have under estimated the true prevalence of alcohol intake in early pregnancy. An anonymized study including all comers would be required to definitively answer this question. Nevertheless, our results are consistent with the results of standard antenatal assessment in our unit. Between 2022 and 2024, there were 44 women in the urban center who self-identified as consuming alcohol during pregnancy and were referred to the medical social work team.²⁰ This represented 0.22% of the 20177 women who delivered in the unit over the triennium and is not significantly different from the positivity rate in our study-0.41% ($p=0.28$). There is also the possibility of behavior change with abstinence in advance of medical appointments, which may affect the results.

5 | CONCLUSION

In summary, this study suggests that significant or heavy alcohol intake in early pregnancy in Ireland is not as frequent as previously believed. Measurement of ethanol and EtG in urine has high acceptability and may be a useful adjunct to standard history taking in the antenatal clinic.

AUTHOR CONTRIBUTIONS

Ciara A. McCormick study design, data collection, and manuscript preparation. Grace Mealy study coordination, data collection, and manuscript preparation. Caroline Donaghy data collection and analysis. Patricia Gordon data collection. Elizabeth Dunne study design and manuscript preparation. Pauline Carroll data collection. Alfonso Rodriguez-Herrera, Conrado M. Cusnaider study design and manuscript preparation. William Ebbitt study design and data analysis. Peter A. McCormick study design, data analysis, data interpretation, and manuscript preparation. Fionnuala M. McAuliffe study design, data interpretation, and manuscript preparation.

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CONFLICT OF INTEREST STATEMENT

The authors report no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

This study was approved by The National Maternity Hospital Research Ethics Committee (EC18.2023) on April 24, 2023 and The Research Ethics Committee, HSE, South East on February 25, 2024. Written informed consent was obtained from study participants.

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