

ORIGINAL ARTICLE

A Clinical Audit of the Process of Care for Women with Gestational Diabetes Mellitus in a Malaysian Public Polyclinic

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ABSTRACT

Introduction: Proper gestational diabetes mellitus (GDM) care is essential for optimal control and thus prevents adverse perinatal outcomes. This audit aimed to determine the quality of GDM care provided by a public polyclinic.

Methods: The audit was performed on the clinic-based medical record of GDM patients who had undergone at least three prenatal follow-ups and one postnatal follow-up between January and November 2012. Patients with pre-existing diabetes mellitus were excluded. **Results:** A total of 74 medical records were audited and it showed that 94.6% of patients were of age 25 and above, 91.9% were Malays, 71.6% were multigravida and 98.6% had risk factors of GDM. 54.1% of diagnoses were made during the second trimester, while 25.7% and 20.2% of cases were detected during the first and third trimester respectively. All of the GDM patients had their weight and blood pressure monitored, 85.1% had their fundal height checked as scheduled and 85.1% were referred for diet counselling. 81.9% and 100% of GDM patients who were not on treatment and on treatment correspondingly had their blood sugar profile monitoring done as recommended. Only 13.5% of GDM patients were given prenatal family planning counselling and 35.1% were given a six weeks' postnatal oral glucose tolerance test appointment. Monthly ultrasound screening and HbA1c monitoring was done in merely 51.4% and 58.1% of the GDM patients respectively. **Conclusion:** The GDM care process in this public polyclinic could be improved further to achieve the standard recommendations.

Keywords: Gestational diabetes, Delivery of healthcare, Medical audit, Standard of care, Primary health care

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INTRODUCTION

Gestational diabetes mellitus (GDM) is a hyperglycaemic condition with first onset or recognition during pregnancy and is most often diagnosed through prenatal screening (1). GDM affects between 2% and 7% of pregnant women of all pregnancies worldwide and its prevalence varies between different population and studies (2, 3). In Malaysia, the prevalence of GDM was 18.3% and 11.4% in a public health clinic (4) and in a university-affiliated hospital (5) respectively. This rate is still significantly higher than that in most western populations.

The main purpose of identifying GDM is to detect pregnant women at risk of adverse perinatal outcomes (6). Untreated GDM not only had resulted in increased perinatal mortality rate up to fourfold compared with that of controlled GDM but it also resulted in perinatal

morbidity. These include macrosomia, primary caesarean delivery, clinical neonatal hypoglycaemia, hyperinsulinemia, preterm birth, shoulder dystocia and/or birth injury, sum of skinfold thickness of above the 90th centile, per cent body fat of more than 90th centile, admission for neonatal intensive care, hyperbilirubinaemia and preeclampsia (7). GDM women who are intensively treated during pregnancy actually had reduced risk of macrosomia, neonatal hypoglycaemia with glucose infusion, birth trauma, neonatal intensive care and shoulder dystocia while risks of complications such as pre-eclampsia and caesarean section were inconsistent (8). Additionally, intensified treatment of GDM reduces serious perinatal morbidity and may also improve the woman's health-related quality of life (9). Apart from that, women who are diagnosed with GDM are at high risk of developing diabetes mellitus (DM) later in life whereby about 10% of them have DM soon after delivery and the rest appear to develop DM at rates of 20–60% within 5–10 years after the index pregnancy in the absence of specific interventions to reduce their risk of DM (10). Therefore it is prudent that GDM is timely diagnosed followed by an appropriate treatment and monitoring.

Based on the Malaysian Clinical Practice Guidelines on Management of Type 2 Diabetes Mellitus 4th edition (CPG-2009) (11), ideal glucose levels should be achieved and maintained and via a 4-6 weekly HbA1c monitoring(11). The incidence of pre-eclampsia, shoulder dystocia and macrosomia are greatly reduced with treatment consisting of diet modification, insulin and glucose monitoring (12). Women with GDM should have OGTT test performed 6 weeks after delivery to detect diabetes and pre-diabetes (13). In patient with GDM, this standard of care is important for achievement of glycaemic control and hence minimizes both maternal and foetal complications of diabetes (14). Additional components in the process of care for DM in pregnancy apart from the above mentioned includes foetal surveillance, pre-eclampsia prophylaxis in pregnant women with pre-existing diabetes and decision on timing and mode of delivery (15). Foetal surveillance using ultrasound scan should be performed monthly from 28 to 36 weeks of gestation. Ultrasound-guided management reduces the risk of large and small for gestational age, and macrosomic babies (16). According to National Institute for Health and Care Excellence (NICE), GDM patients with maternal or foetal complications should deliver by 40 weeks and 6 days gestation (17). Mode of delivery should be individualised, taking into consideration the estimated foetal weight and obstetric factors. However with the publication of newer guidelines ie Management of Diabetes in Pregnancy 2017, HbA1c is no longer necessary for the monitoring of the glucose control, as there is no evidence on the effectiveness of HbA1c monitoring in predicting adverse outcomes in pregnancy. As for the timing of delivery in women with gestational diabetes mellitus (GDM), those with no complications and good glycaemic control on diet alone, delivery should be planned before 40+0 weeks, for those requiring oral antidiabetic agents or insulin, delivery should be planned between 37+0 and 38+6 weeks and for those who develop maternal or fetal complications, elective delivery before 37+0 weeks should be considered (13).

As defined by NICE, "A clinical audit is a quality improvement procedure that aims to enhance the patient care and outcomes through systematic review of care against explicit criteria and the application of change". It allows the evaluation of either the structure, the process or the outcome of care against a standard practice endorsed by clinical guidelines (18). Furthermore, the findings of the audit can be used to improve the health care delivery by implementing changes and monitoring outcome to confirm improvement when indicated (19). In view of this, this partial clinical audit was undertaken to determine the quality of GDM care process at one of the public health clinics.

A clinical audit is justified as it is a useful tool that permits evaluation of the quality of care for patients with GDM of this clinic. This current audit was planned following a

pilot audit of 20 GDM records by the Family Medicine Specialist (FMS). The unpublished internal audit yielded majority unachieved results despite implementing a lower target of performance. In view of limited local literature on audit of GDM care in primary care setting, the FMS had invited us to execute an external audit to provide insights towards the clinic' performance and later may aid the clinic in drawing and implementing certain measures to overcome the deficiencies.

MATERIALS AND METHODS

This was a retrospective partial clinical audit conducted in January 2013 which involved the first three stages of a clinical audit, without making improvement (fourth stage) and re-audit to sustain improvement (fifth stage). The purpose of auditing the patients' medical records was to evaluate the quality of GDM care provided by a rural public polyclinic in Selangor between January 2012 and November 2012. It has a basic in-house laboratory, an X-ray unit, an out-patient clinic unit, a Maternal and Child Health Clinic (MCHC), an accident and emergency unit, a reproductive health unit, methadone maintenance therapy unit, quit smoking care, a dental clinic and school health clinic.

The MCHC provided care to the prenatal and postnatal women, children below 6 years old and other related services such as PAP smear, family planning and childhood vaccination. The FMS oversaw patients in all units including the MCHC, while two medical officers (MOs) were based in MCHC for a certain period of time on rotation basis. The FMS provided consultation to cases referred by the MOs while the MOs attended to all cases referred by the nurses. The staff who manned the MCHC unit included a Matron and a Sister who supervised the process of care of patients and administration of the clinic. The nine community nurses took charge in terms of carrying out the process of care for the patients including documentation. This MCHC implemented traditional hardcopy record and filing system whereby patients kept their brief home-based medical record (HBMR) while the patients' clinic-based medical record (CBMR) were filed in the MCHC. Both HBMR and CBMR were updated by the staff.

Regarding the standard process of care of GDM, this MCHC neither had a dedicated team nor designated days for GDM follow ups. All GDM patients were seen by the MO and if indicated, were referred to the FMS for further care. Appointments for monthly scans and fortnightly blood sugar monitoring were given by the MOs during their reviews. The family planning counselling were done opportunistically, either at any time during ante natal or post-partum, though most counselling and OGTT appointment date were given at one month post-partum visit. Venous blood sugar profile (BSP) is done four times a day at the clinic with a two weekly blood monitoring for all GDM patients on insulin

following diagnosis. Meanwhile, GDM patients who are not on treatment need a monthly and two weekly BSP for a POG of below 28 weeks and 28 weeks and above, correspondingly.

After a thorough discussion with team members, considering resource limitations for the laboratory investigations and reviewing the literatures, we have decided to assess these important indicators in this audit with individual target level of performances such as referral to nutritionist/dietitian (80%), HbA1c (50%), prenatal family counselling (80%) and postnatal OGTT appointment (70%). The target levels of performance for weight, blood pressure and uterine fundal height measurement, prenatal family planning counselling, ultrasound screening, HbA1c test and postnatal OGTT appointment date were set at 100%.

The demographic characteristic of the patients consist of the age group and race while the clinical characteristics include the patients' pregnancy status, period of gestation (POG) and risk factors for GDM. The risk factors, as documented on the front page of the patients' CBMR (Table I) comprise a body index mass of more than 27kg/m², previous macrosomic baby weighing 4 kg or above, previous GDM, first-degree relative with diabetes, bad obstetric history (such as unexplained intrauterine death, congenital anomalies and shoulder dystocia), glycosuria at the first prenatal visit, current obstetric problems for example essential hypertension, pregnancy induced hypertension, polyhydramnios and current use of steroids as well as age above 25 years old. These risks are according to the CPG-2009 (11) and standards of medical care in diabetes by the American Diabetes Association (20).

Table I: Demographic and clinical characteristics of 74 patients included in the audit

Characteristics	Frequency	Percentage (%)
<i>Age groups (years)</i>		
More and equal to 25	70	94.6
Less than 25	4	5.4
<i>Race</i>		
Malay	68	91.9
Chinese	0	0
Indian	4	5.4
Others	2	2.7
<i>Gravida</i>		
Primigravida	21	28.4
Multigravida	53	71.6
<i>Period of Gestation (POG) at diagnosis</i>		
	19	25.7
First trimester	40	54.1
Second trimester	15	20.2
Third trimester		
<i>Risk Factors</i>		
With Risk Factors	73	98.6
Without Risk Factors	1	1.4

All researchers were involved in the data collection. The standardization of data collection was preserved as training session was given prior to data collection and the information was collected by two persons at one time for countercheck purpose. On top of that, data was checked for errors following the data entry. The CBMR of the patients diagnosed with GDM who had at least three antenatal follow-ups and one postnatal follow-up at any time postpartum between January 2012 and November 2012 were chosen. Patients with pre-existing type 1 and type 2 DM were excluded. A total of 74 patients' CBMR were selected using the universal sampling method from the dedicated medical records filing cabinet of GDM patients in the MCHC unit. Each of the CBMR was screened for the inclusion and exclusion criteria before recording the data into a structured case record forms. All the indicators of the GDM care process were recorded as 'done' or 'not done'. The data obtained was analysed using Microsoft Excel 2007. For each indicator, the actual level of performance achieved was calculated and compared with the target level of performance. The summary of the processes are summarized in Table II.

Table II: Percentage of the completed process of care as compared to the target level of performance

No.	Indicators of process	Criteria of indicators	Results (percentage)	Target level of performance
1.	Blood Sugar Profile (BSP) Monitoring	Patients not on treatment (n=72) < 28 weeks POG= done monthly ≥ 28 weeks POG = done every 2 weekly	59 (81.9%)*	100%
		Patients on Treatment (n=2) - done 2 weekly after diagnosis	2 (100%)	100%
2.	Referral to nutritionist / dietician	Done at least once	63 (85.1%)	80%
3.	Weight	Done at every follow up	74 (100%)	100%
4.	Blood Pressure	Done at every follow-up	74 (100%)	100%
5.	Uterine fundal height	Done at every follow-up	63 (85.1%)*	100%
6.	Prenatal Family Planning Counselling	Done at any time prior to delivery	10 (13.5%)*	80%
7.	Ultrasound screening	Done monthly since conception	38 (51.4%)*	100%
8.	Hb _{A1c}	Done monthly after diagnosis	43 (58.1%)	50%
9.	Postnatal OGTT appointment	Given at 6 weeks post-delivery	26 (35.1%)*	70%

*Not achieving target level of performance

In order to explain the findings of this audit, we referred to both the standard process of care being practiced by the clinic and the CPG-2009 (11), relevant during the time of this clinical audit in 2012. In addition, we also looked at similar literatures, such as previous audits on GDM care at public clinics and we interviewed the staff of the MCHC.

RESULTS

Out of the 74 patients with GDM, 94.6% of patients were of age 25 and above. Majority of them (91.9%) were Malay and 71.6% were multigravida (Table I). As for the POG at the time of GDM diagnosis, 25.7% were diagnosed during the first trimester while 54.1% and 20.2% were confirmed during the second trimester and third trimester respectively. 98.6% (n=73) of them have risk factors for GDM.

All GDM patients who were on insulin treatment had their suggested 2 weekly blood sugar profile (BSP) carried out following diagnosis. Nevertheless, only 81.9% of GDM patients who were not on insulin treatment had their BSP done as recommended. In view of referrals to other services, 85.1% of GDM patients were referred at least once to either a nutritionist or dietician for diet counselling. On the other hand, only 13.5% of them were given at least once prenatal family planning counselling. Blood pressure and weight were monitored for all (100%) GDM patients but only 85.1% of them had their fundal height examined at each follow-up. Monthly ultrasound and HbA1c screening were performed for 51.4% and 58.1% of the GDM patients correspondingly. Only 35.1% of patients were given a 6-weeks post-natal oral glucose tolerance test (OGTT) appointment (Table II).

DISCUSSION

Most of the GDM patients in this partial clinical audit were multigravida (71.6%). This finding is fairly similar to the finding in previous studies conducted in Asia, such as the GDM women with multigravida were ranging from 63.1% - 87.6% (21, 22). Majority of the audited patients have underlying risk factors for GDM. This is not surprising as pregnant women with positive risk factors do have a high tendency to develop GDM (23). Increased risk factors for GDM were reported with higher maternal age, body weight and BMI, previous history of GDM, macrosomia and family history of diabetes (24, 25)

In this audit, 100% of GDM patients who were on insulin treatment (n = 2) had their recommended BSP done following diagnosis, hence achieving the target. Conversely, the target level of performance was not achieved for GDM patients who were not on insulin treatment. The blood glucose targets for both GDM patients who

were not on insulin treatment and those who were on insulin treatment are as follows: fasting or pre-prandial: ≤ 5.3 mmol/L, 1-hour post-prandial: ≤ 7.8 mmol/L, 2-hour post-prandial: ≤ 6.7 mmol/L. (13). Insulin should be initiated if the targets are not achieved despite counseling on correct timing of BSP monitoring and adequate diet control. Verbal comments by the nurses on the reasons for the unachieved level of performance for this indicator were due to the lack of consistent documentation of the BSP in CBMR. This is because at most times, the HBMR is readily available with the patients when BSP are reviewed, especially after working hours. Besides, based on the home addresses stated in the CBMR, some patients' homes were far from the clinic. This distance issue which was further confirmed by the nurses have some influences on the patients' frequent attendance for BSP. On the other hand, the target performance for prenatal referral to a weekly visiting dietician/nutritionist was achieved. For this clinic, group diet counseling can be structured by the weekly visiting dietician/nutritionist. This finding is also seen in a similar audit of another public clinic whereby dietician/nutritionist referral was done for 76.3% of GDM mothers despite not having a in-house dietician/nutritionist (26).

Weight and blood pressure checking had reached its target level of performance as nurses usually perform triaging prior to consultation by the doctor, at the triage counter for all patients regardless of their appointment date. Nevertheless, fundal heights were measured by the doctor in the consultation room only for the patients with a scheduled visit, rather than to all patients. This was a probable reason why only 85.1% of GDM patients had the fundal height measured, hence not achieving the target level of performance. A study of 2941 women reported SFH to be less predictive with a sensitivity of 27% and specificity of 88% (LR+ 2.22, 95% CI 1.77–2.78; LR– 0.83, 95% CI 0.77–0.90).(27) Factors such as maternal obesity, abnormal foetal lie, large fibroids, hydramnios and foetal head engagement result in the limited predictive accuracy of SFH measurement. Moreover, SFH has significant intra- and inter-observer variation (28,29) and serial measurement may improve predictive accuracy (30).

Despite achieving the target performance for monthly HbA1c monitoring of 50%, adequate budgeting for HbA1c reagents should be made available to ensure continuity of monitoring. The result was not unforeseen of a government polyclinic which has an established in-house medical laboratory managed by a medical laboratory technician without much budget constraint. HbA1c test reflects average plasma glucose level during past 3 months. However, it does not reflect accurate glycaemic control during pregnancy as it is influenced by the life span of red blood cells and iron demand. Besides, HbA1c is significantly higher in women with iron deficiency anaemia. Increasing demand of iron during the second and third trimester contributed to a

much higher level of HbA1c (31). However study also reported that HbA1c level in late pregnancy of GDM mothers is a good predictor for hypoglycaemia in the new born (32). Nevertheless HbA1C were performed in this public polyclinic as it was used as a strategy to select high-risk women for lifestyle interventions to prevent diabetes (33). In addition, measurement of HbA1c level for known diabetic women during pre-conception period is recommended to achieve good glycaemic control, with value aimed at less than 6.5% (11, 34)

Another less desirable performance noted was the provision of a 6 weeks postnatal OGTT appointment with only 35.1% of GDM patients were given this important appointment date. Postnatal follow-up with OGTT is crucial as some of these patients may manifest impaired glucose tolerance (IGT) or diabetes mellitus. If the postnatal evaluation is normal, patients should be instructed on the symptoms of diabetes and have an annual evaluation of glucose metabolism by a fasting plasma glucose level. According to the staff, the postnatal OGTT appointment date was not documented in the patients' CBMR but was instead documented in their HBMR. Likewise, monthly ultrasound screening did not reach its target although it should be done monthly to detect foetal growth and complications such as macrosomia and polyhydramnios. However, there were only 51.4% (n = 38) of mothers with GDM here who have had their monthly ultrasound scans done. As revealed by the staff, ultrasound screening may have been done in the private clinics and were documented only in the patients' HBMR which were readily available at the times the scans were done, but were then not redocumented in their CBMR during subsequent consultations with the doctors. Further, there was only one unit of ultrasound machine in this MCHC during the clinical audit. This may contribute to the low performance of this indicator in this audit.

The worst performance was prenatal family planning counselling whereby only 13.5% of GDM patients were given at least once prenatal family planning counselling. The reason for this as stated by the staff was the doctors who saw the referred GDM patients claimed that they had provided verbal personal counselling without proper documentation due to higher numbers of patients as compared to available doctors. There were only one FMS who were based in the outpatient unit most of the time, and two rotational MOs attending to all referred cases of mothers and children in MCHC. During the clinical audit, the daily numbers of referred cases reached up to 100 cases that each doctor attended to about 30 patients each day. Other MCHC patients who were not referred to the doctors for prenatal and postnatal care received routine documented group prenatal family planning counselling from the nurses.

The findings of this clinical audit were presented to the FMS via a formal hard copy report and discussion.

Nevertheless, since we did not complete the audit cycle due to time and resources constraint, we were not involved with any brainstorming sessions to improve the quality of care.

RECOMMENDATION

In order to improve the level of performance of GDM care in this clinic, the following recommendations which are based on the shortfalls noted during this audit and the clinic' available resources are suggested. A few shortfalls due to failure of documentation in patients' CBMR include BSP among GDM patients who were not on insulin treatment, the provision of a 6 weeks postnatal OGTT appointment, monthly ultrasound screening, prenatal family planning counselling and fundal heights measurement by the doctors. Further, the absence of a formal process to ensure timely postnatal OGTT demands a proper system to be in place. To overcome the documentation issue, we recommend an electronic medical record system instead of the current traditional hardcopy medical record. This electronic health record system has actually been implemented and replaced the traditional manual record system in the outpatient, emergency and laboratory units of this public polyclinic. It is primarily clinical in focus, designed to provide patient details and health care provider decision, standard process of care and next appointment dates. An electronic checklist and reminders on GDM care processes can be installed as well. All these data can be backed-up to prevent any loss of data, retrieved conveniently, accessible to the allocated staff at any time and able to detect missed processes or defaulters.

If an electronic medical record system is not feasible due to cost, a manual general clinic-based record book (GDM registry) with a manual checklist of standard GDM care processes can be created. This GDM registry is mainly used for the recordings of the names of all patients who visited the MCHC unit and provide accurate, complete, valid and reliable GDM entries, in order to determine the actual numbers of GDM patients who attended the clinic. The manual checklist on the other hand, must be made available on the front pages of both patients' CBMR and HBMR as it displays in-depth sections such as GDM screening, diagnosis, treatment, dietary restriction and physical exercise (35). Completed, these checklist shall be ticked manually by the health care staff as an acknowledgment that it has been executed (36). This front page checklist should be scrutinized by the nurses prior to consultation and audited regularly by the Sister. Any missed processes can be identified, rectified promptly and have been shown to reduce harm in some health care department (37).

Another shortfall noted was the BSP of GDM patients who were not on insulin treatment. Education on the importance of BSP monitoring ought to be delivered to all GDM patients to safeguard their understanding as

education was shown to improve patient's knowledge and awareness on their health status, and increase their seriousness toward recovery, therefore enhancing their attendance as scheduled (23). For patients who face barriers in attending the four times a day BSP appointment at the clinic, a home-based BSP done by the patients or their family using a glucometer loaned by the clinic can be substituted. Another alternative is delegating the BSP to the staff at the rural clinics which is nearest to the patients' residency. We also suggest a short-messaging-system (SMS) to remind patients at least one day prior to the BSP schedule. Besides that, we also propose a defaulter tracing program at the end of each clinic day to trace patients who failed to attend the BSP. These are worth trying, as trials using mobile technology-based intervention to improve health care delivery services showed modest benefits.

The worst underperformance noted in this clinical audit was the prenatal family planning counselling. Traditionally, patients with GDM were counselled by the doctors personally during consultation while other patients who were not referred to the doctors were counselled in groups by the nurses. Improper documentation by the doctors can be addressed by the manual or electronic checklist and medical record system. Whereas to safeguard that the counselling is delivered timely, all patients with GDM can be enrolled into the existing group prenatal family planning counselling for other patients which is provided by the nurses or doctors at monthly interval. It induces understanding and motivation among the patients to adopt a healthy lifestyle such as weight loss and exercise that can reduce GDM risk and overall diabetic morbidity while improving glycaemic control (36). Intensified counselling during antenatal visit was shown to improve the postnatal complications (259). Further, all patients should receive contraceptive advice and counselling regarding future pregnancies (36) as they were proven to be effective to reduce the risk of diabetes among women with previous GDM (38).

To strengthen their knowledge, cooperation and responsibility sharing of the healthcare providers, a continuous medical education on the best practice of GDM care should be made available (39). Nurses should check whether the standard process had been done and perform the routine examination at every visit before sending the GDM patients to the doctor. All these changes however need monitoring by the superior staff to ensure sustainability. Finally, to complete the cycle of a clinical audit, changes of practice based on the above mentioned recommendations followed by further monitoring should be in place to confirm improvement in the healthcare delivery.

LIMITATIONS

The absence of a proper GDM registry during the audit

limits this retrospective partial clinical audit. There was a possibility of missing data, illegible or incomplete documentation and unknown actual number of GDM patients. In addition, the filing of records was not systematic enough which had led to difficulty in tracing the data, laboratory results as well as the laboratory orders forms. Furthermore, the audit findings are limited by the issue of discordance between the home-based and clinic-based records. Finally this clinical audit is a part of the complete clinical audit cycle, without the application and monitoring of change and its' outcome on healthcare. Hence, it is hoped that a complete cycle can be conducted in near future to enhance its usability.

CONCLUSION

In conclusion, there is a gap between guidelines and clinical practice in the provision of GDM care as shown by this audit. The quality of care in carrying out BSP among GDM mothers not on insulin, adherence of ultrasound service, counselling of family planning and appointment for post-partum OGTT were found to be suboptimal hence needing certain measures to improve it. With combination of the patients and healthcare providers' education, upgrading the systems involved and frequent clinical audit could improve the quality of GDM care in this public polyclinic. This clinical audit contributes towards the literature on the management of GDM in primary care and may serve as a baseline data which can guide future clinical audit.

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