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BACKGROUND

An estimated 2 – 9 % of all pregnancies are complicated by gestational diabetes mellitus (GDM).¹ While untreated GDM is associated with increased patient morbidity, appropriate management results in significantly improved maternal and infant health outcomes.^{2,3}

The current Canadian Diabetes Association (CDA) Clinical Practice Guidelines recommend lifestyle modifications as a first-line treatment, followed by initiation of insulin therapy if glycemic targets are not achieved within 2 weeks.² Unlike insulin, oral hypoglycemic agents cross the placenta and are cleared at an increased rate during pregnancy; consequently, their use is not recommended by the 2013 CDA guidelines.²

However, a growing body of recent evidence supports the safety and efficacy of oral hypoglycemic agents during pregnancy.³ In light of these findings, many international guidelines now recommend metformin as the primary drug therapy for GDM.^{4,5}

In January of 2016, the diabetes management team at Sunnybrook Hospital introduced the 'Metformin First' (MF) protocol at their Diabetes in Pregnancy Clinic. Metformin is now offered to all patients at the clinic requiring drug therapy for GDM treatment.

Given that oral agents are less expensive than insulin, easier to administer and are often better accepted by patients, it is hoped this initiative will result in improved patient satisfaction.⁵ Further rationale for the protocol includes potential for improved clinic efficiency initiation of insulin therapy is a resource-intensive process, requiring individualized patient training and continuous staff support and monitoring.

OBJECTIVES

The primary objectives of this study are:

- To evaluate the safety and efficacy of metformin use for the management of GDM
- To determine if the introduction of the MF protocol has resulted in improved patient satisfaction and efficiency at the HRO clinic.

METHODS

This is a mixed methods study including a retrospective chart review and an anonymous patient satisfaction survey.

CHART REVIEW: A retrospective chart review was conducted of all new GDM patients seen at the clinic prior to (Jan-Jul 2015) and following (Jan-Sept 2016) implementation of the MF protocol.

Patients were excluded if they had type 1 or 2 diabetes, a multiple-birth pregnancy, if they delivered outside of Sunnybrook or if their pregnancy data was not available. Eligible patients were categorized into four treatment groups – lifestyle alone, insulin, metformin or metformin+insulin.

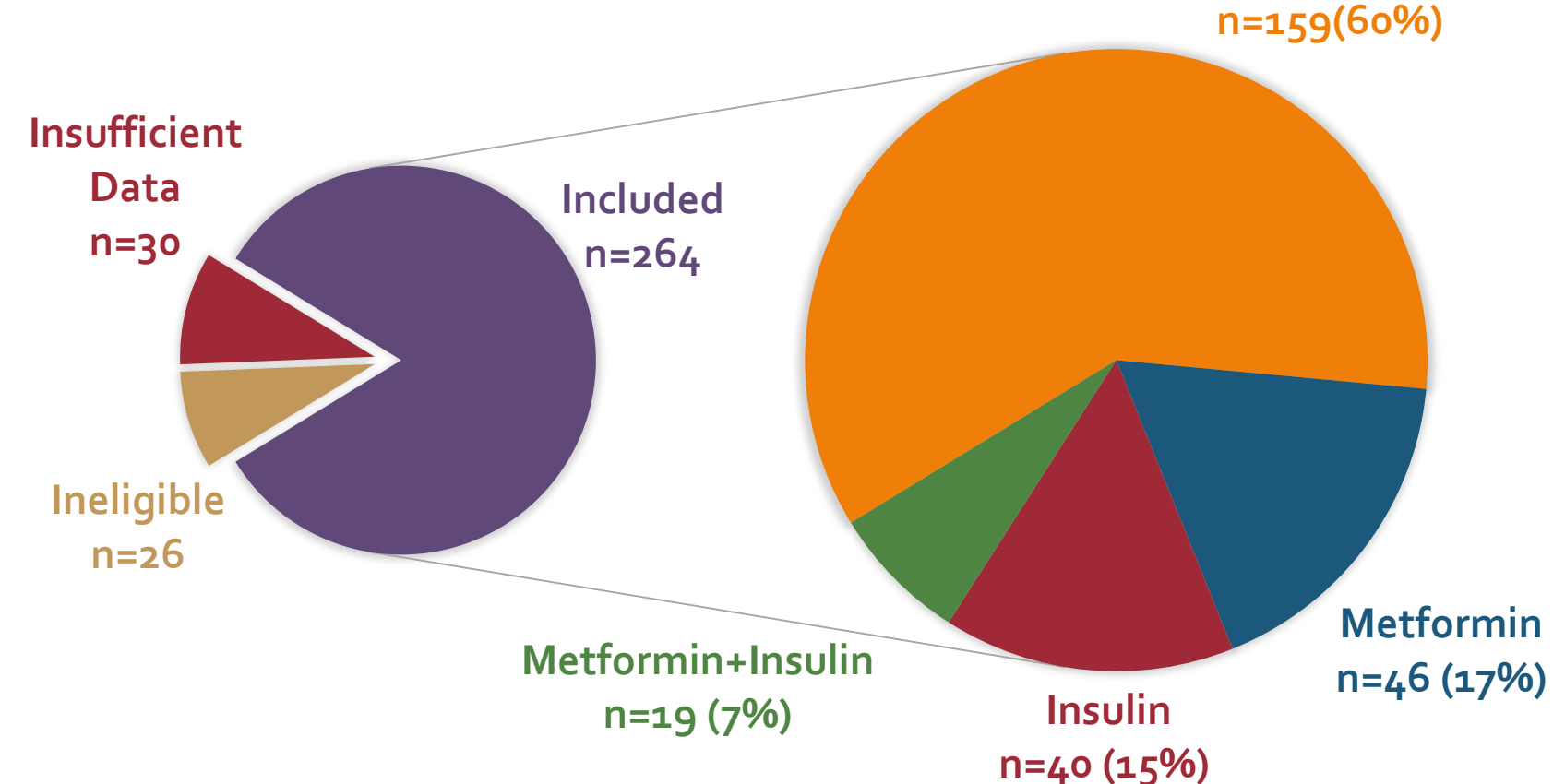
PATIENT SATISFACTION SURVEY: A prospective patient survey was administered to evaluate impact of the protocol on patient satisfaction and clinic efficiency. Patients responses were compared to a similar satisfaction survey conducted in 2013, prior to implementation of the MF protocol.

RESULTS: CHART REVIEW

1. Demographic Data

1.1 DISTRIBUTION OF PATIENTS ACROSS TREATMENT GROUPS

Total charts reviewed =

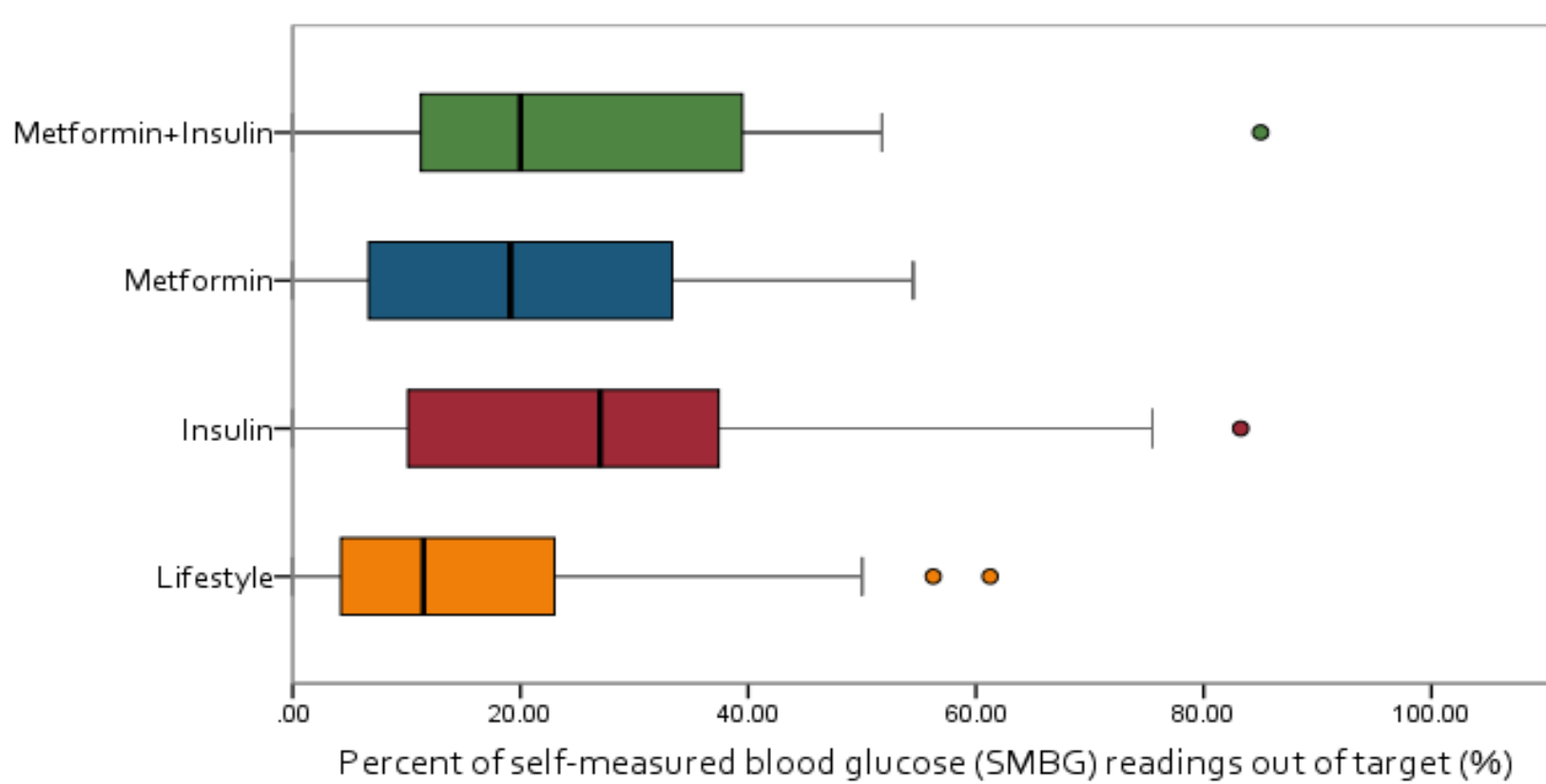


1.2 Maternal Baseline Characteristics					
	Lifestyle	Metformin	Insulin	Metformin + Insulin	Total
Age - yrs	34.6 ±4.4	34.2 ±3.2	34.6 ±4.2	35.1 ±4.4	34.7 ±4.2
Parity	1.7 ±0.9	1.8 ±0.6	1.7 ±0.8	2.1 ±1.1	1.7 ±0.9
Pre-pregnancy Weight - kg*	62.7 ±12.6	73.4 ±17.9	74.5 ±20.8	91.0 ±19.0	69.2 ±17.8
Pre-pregnancy BMI*	24.6 ±4.3	28.5 ±6.2	28.5 ±7.0	33.5 ±6.8	26.8 ±6.0
Weight at diagnosis - kg*	73.5 ±13.2	83.8 ±17.3	85.7 ±19.3	103.9 ±20.3	79.5 ±17.8
GCT value	9.8 ±1.4	10.6 ±1.9	10.6 ±1.7	10.8 ±2.2	10.1 ±1.8
Fasting OGTT *	4.7 ±0.7	5.5 ±1.0	5.3 ±0.8	5.3 ±0.3	4.9 ±0.8
One hour OGTT	10.6 ±1.2	10.8 ±1.3	11.1 ±1.7	10.4 ±1.0	10.7 ±1.3
Two hour OGTT	9.1 ±1.4	8.4 ±1.5	8.6 ±1.5	8.4 ±1.5	8.9 ±1.5

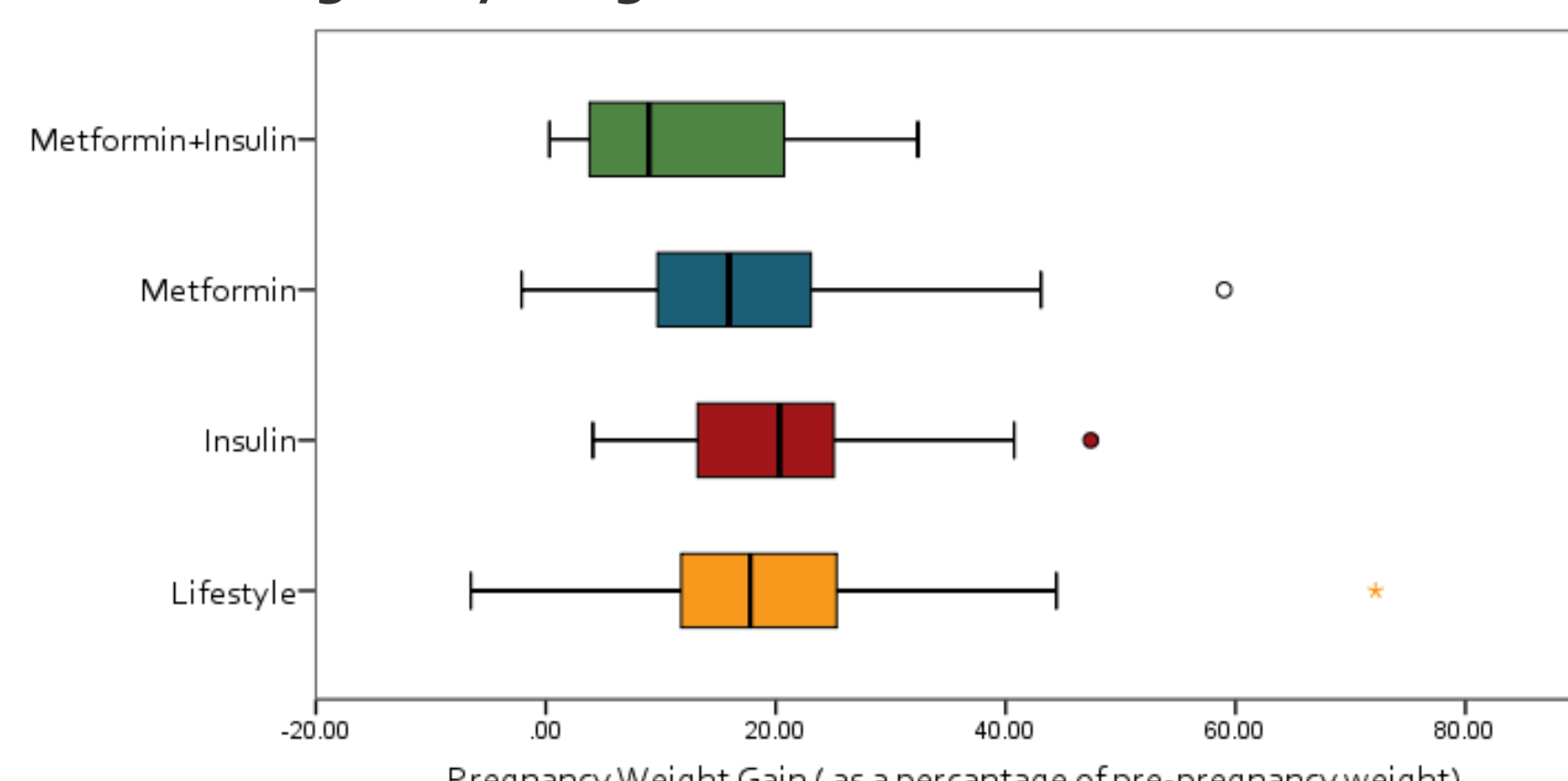
* MANOVA results show significant difference at p < 0.05 between treatment groups

2. Patient Outcomes Across Treatment Groups

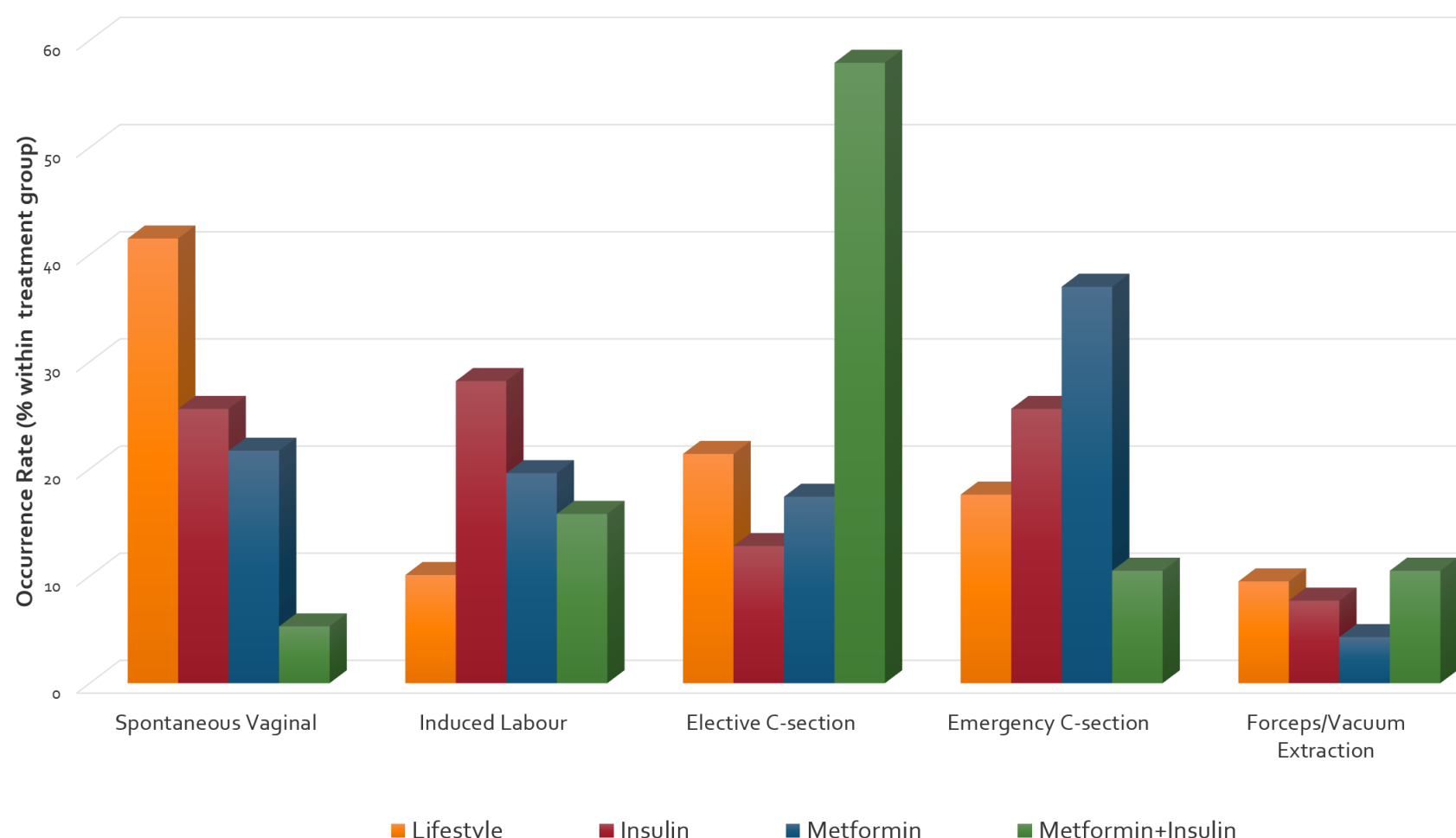
2.1 Blood Glucose Control



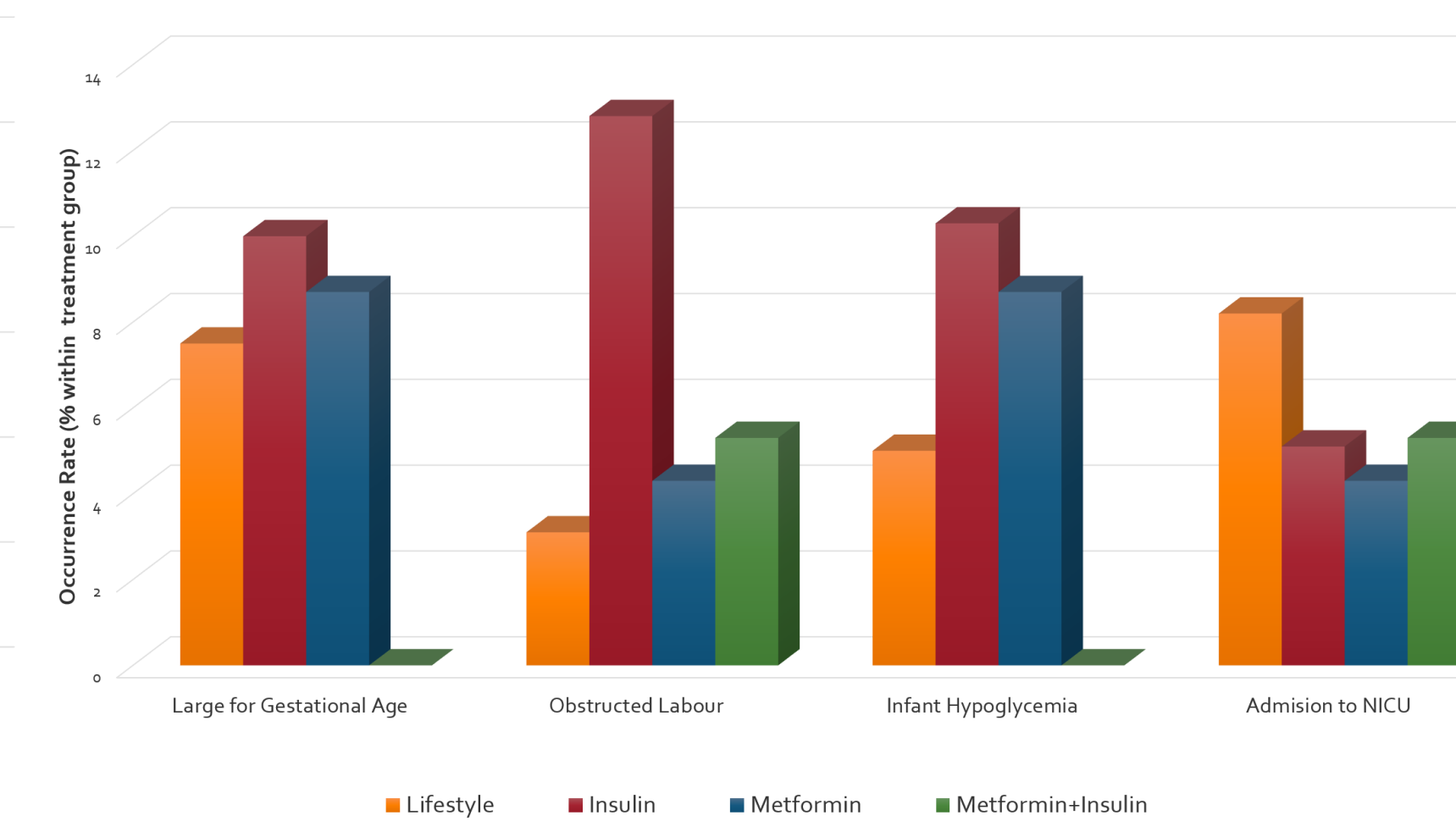
2.2 Pregnancy Weight Gain



2.3 Labour Outcomes



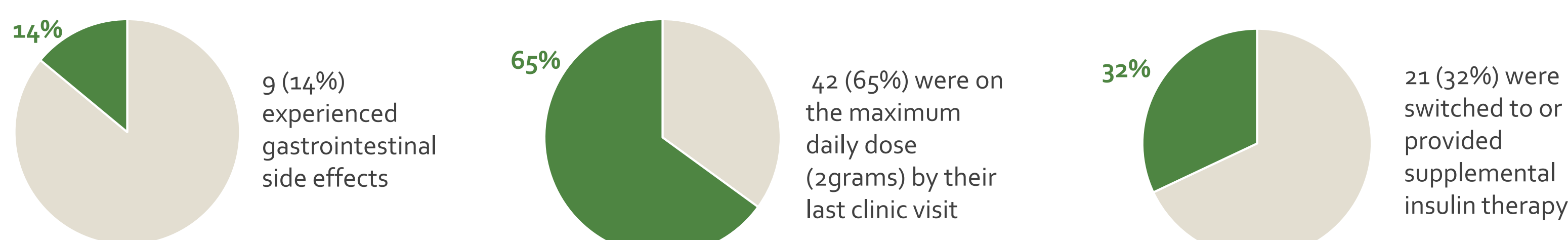
2.4 Perinatal Complications



The average percentage of SMBG readings out of target was significantly lower in the lifestyle group (mean=15.6% ±14.3) as compared to the insulin group (mean=27.4% ±21.2, p=0.02). There were no significant differences in weight gain, labour outcomes or perinatal complications across the four treatment groups.

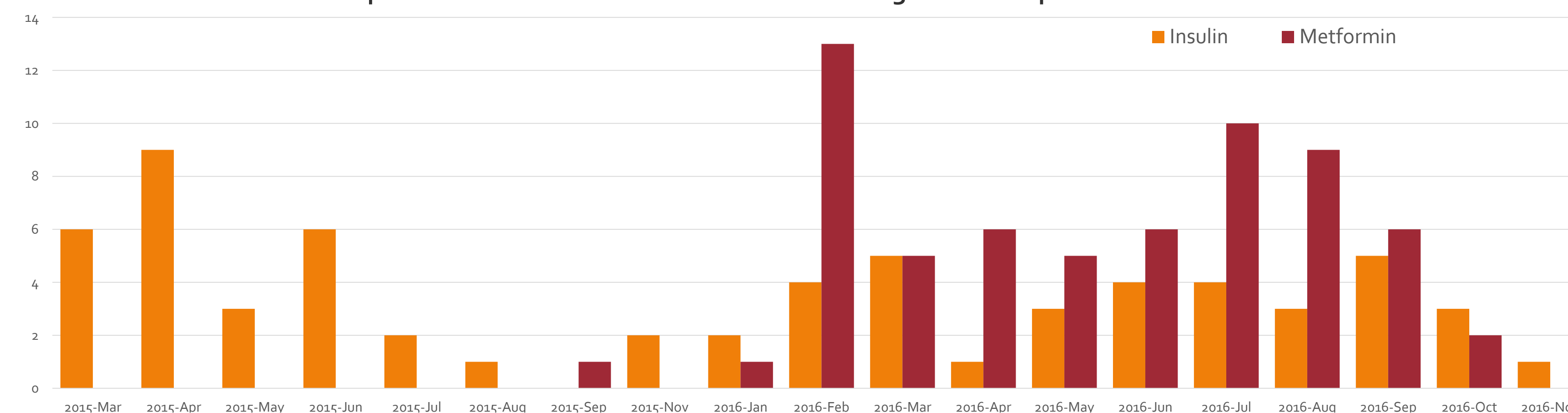
3. Metformin Profile

65 patients were initially started on metformin:



4. Clinic Efficiency

Number of patients started on insulin or metformin during the review period



Following implementation of the MF protocol, the percentage of clinic patients started on insulin has decreased significantly (33% in 2015 vs 17% in 2016, p=0.003).

RESULTS: PATIENT SURVEY

5. Patient Satisfaction

5.1 Survey Responses by Treatment Group



5.2 Patient satisfaction scores prior to and following MF protocol

	Year	N	Mean Score	Std. Deviation
Satisfaction score - out of 5	2016	40	4.68/5	0.58
	2013	40	4.30/5	0.94

*statistical significant results (p=0.014)

CONCLUSIONS

- There are key variations in the baseline characteristics of patients with GDM who later require medication therapy and those managed with lifestyle alone.
- Metformin is comparable to insulin in glycemic control and pregnancy outcomes for women with GDM.
- Introduction of the 'Metformin First' protocol has resulted in improved patient satisfaction and clinic efficiency.

FUTURE IMPLICATIONS

These findings provide the clinic with valuable insights regarding the impact of the recently initiated 'Metformin First' protocol. The observed benefits of this initiative will help inform future adjustments to patient care both within Sunnybrook and at other local hospitals.

CITATIONS

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