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ORIGINAL ARTICLE

Optimizing Diabetes Management During Type 1 Diabetes Pregnancy with Automated Insulin Delivery Therapy: Clinical Impact and Economic Consequences in Spain

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Abstract

Background and Aim: The CamAPS FX automated insulin delivery (AID) system is extensively evaluated and uniquely tailored for T1D pregnancies. This study evaluated the clinical and economic implications of improving glycemia with CamAPS FX AID compared with the current standard of care (SoC).
Methods: A cost-consequence model was built leveraging data from the AiDAPT study and was adapted to the Spanish health care perspective, using local costs obtained from the literature or hospital databases. As observed in AiDAPT, women treated with AID began with an average glycated hemoglobin (HbA1c) of 7.6% (±1.1) and reached a post-treatment average of 6.0% (±0.5), demonstrating significant improvement in glycemic control. However, in the model, clinical outcomes and the resulting cost impact are based on the incremental 0.3% HbA1c reduction from the first to the third trimester using AID over SoC treatment.
Results: Using CamAPS FX AID instead of SoC in pregnancies complicated by T1D resulted in estimated cost savings of €1,002 per treated woman for the Spanish health care system within the first year of treatment. Of these cost savings, the majority (81%) were driven by reductions in intensive neonatal care admissions, reflecting not only marked financial savings but, more importantly, a reduction in complications and suffering among newborns.
Conclusion: This conservative analysis captures a clinically significant impact and subsequent economic value, despite being based on only a limited number of perinatal complications. This study provides valuable insights to guide clinical practice, shape health care decision-making, and support broader adoption of technologies that improve maternal and neonatal outcomes.

Keywords: type 1 diabetes mellitus, pregnancy, glycemic control, glycated hemoglobin, diabetes complications.

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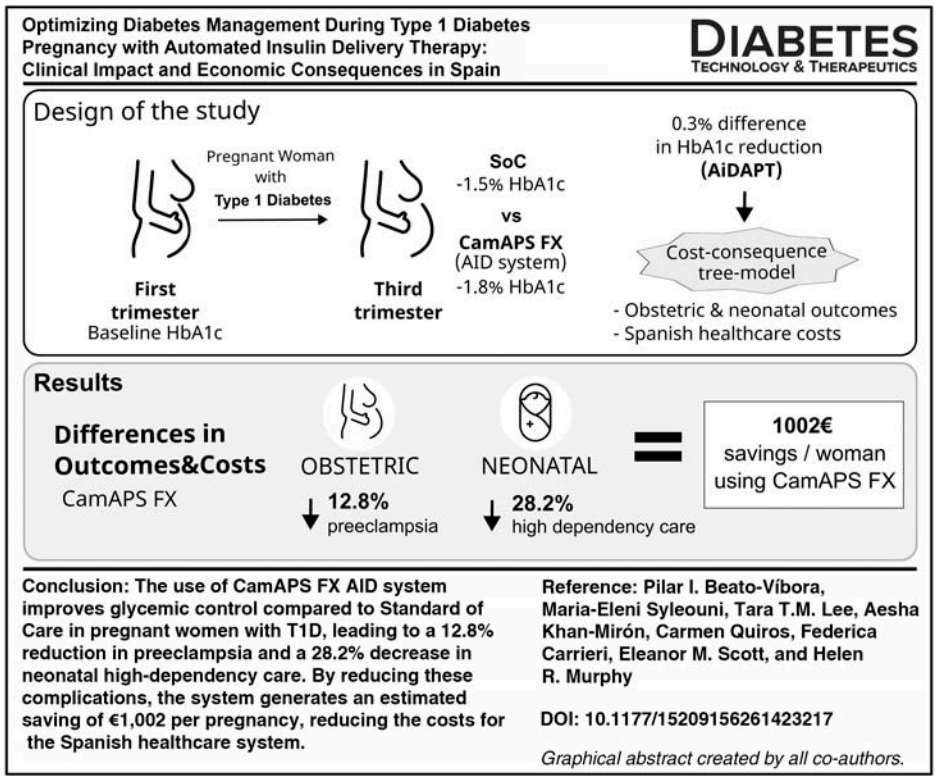

Introduction

Managing type 1 diabetes mellitus (T1D) during pregnancy is a major clinical challenge, as optimal glycemic control is essential to prevent maternal and neonatal complications.[1,2] Clinical guidelines from the UK's National Institute for Health and Care Excellence (NICE), the Spanish Society of Diabetes, and the Spanish Society of Gynecology and Obstetrics recommend maintaining tight glycemic targets throughout pregnancy, typically aiming for a glycated hemoglobin (HbA1c) level below or equal to 6.5% (48 mmol/mol), while minimizing the risk of hypoglycemia.[3–5] Achieving and sustaining these glucose targets during pregnancy have been shown to reduce the risk of preeclampsia and neonatal outcomes, such as preterm birth, admission to neonatal intensive care units (NICU), large weight for gestational age, and perinatal death.[5–8]

In Spain, population-based studies showed that the number of deliveries in women with T1D has increased over time, paralleled with the prevalence of comorbidities and obstetric risk factors.[9,10] During pregnancy, Spanish clinical guidelines are aligned with NICE recommendations, promoting the use of continuous glucose monitoring (CGM), HbA1c measurements every 4–8 weeks, and obstetric follow-up every 2–4 weeks.[11,12] For insulin treatment, either a basal-bolus regimen or a continuous insulin infusion system is recommended.[11,12] Real-world data studies including pregnant women with T1D (PWwT1D) in Spain found that about 59% had at least one comorbidity, highlighting that maternal morbidity and fetal overgrowth remain frequent complications in this population.[9,10] Thus, supporting the use of advanced technologies with the ability to adjust insulin delivery may positively impact maternal and neonatal outcomes, even though no studies with dedicated endpoints are yet available. In this context, and given the increased metabolic demands and clinical complexity during pregnancy—particularly among women with comorbidities—standard insulin regimens may be insufficient to achieve optimal glycemic control, further reinforcing the rationale for adopting automated insulin delivery (AID) systems—particularly hybrid closed-loop (HCL) systems—as a strategy to improve glycemic control and maternal–fetal outcomes.[13,14]

CamAPS FX was the first AID system with a formal regulatory indication for use in pregnancy with T1D, approved in the EU, United Kingdom, and USA, among other jurisdictions.[15] It was developed incorporating pregnancy-specific parameters, has a uniquely predictive adaptative algorithm,[15] and offers the lowest glucose targets. CamAPS FX allows users to set ambitious personal glucose targets down to 4.4–5.0 mmol/L (80–90 mg/dL), such as those recommended during pregnancy.[16]

Its efficacy was assessed in the AiDAPT randomized controlled trial (RCT), conducted in the United Kingdom,[16] in which CamAPS FX significantly improved glycemic outcomes compared to the standard of care (SoC)—either multiple daily injections (MDI) or continuous subcutaneous insulin infusion, both used with CGM. Specifically, CamAPS FX AID led to improvements in maternal glucose Time in Range for pregnancy (TIRp), reductions in hypoglycemia, and lower HbA1c levels.[16]

In contrast, the use of non-pregnancy-specific AID systems during pregnancy has yielded inconsistent or limited

benefits.[17,18] In a real-world cohort study, no statistically significant differences were found in TIRp or HbA1c when comparing off-label AID systems to MDI-based SoC in pregnant women with T1D.[19] Similarly, the CRISTAL RCT, evaluating an advanced AID system, reported no significant improvement in primary glycemic outcomes compared to SoC.[20] The CIRCUIT trial reported significant improvement in primary glycemic outcomes as compared to suboptimal SoC, with notably higher mean glucose in the AID intervention group compared to AiDAPT.[17] These RCT and real-world study[21] findings highlight the clinical relevance of using systems that rapidly adapt to the dynamic physiological state of pregnancy, rather than extrapolating evidence from non-pregnant populations.

A cost-consequence model was developed leveraging the AiDAPT data to assess the clinical and economic impact of improving HbA1c from the first to the third trimester in PWwT1D using CamAPS FX versus standard of care.[22] This study aimed to evaluate the clinical benefits, resource utilization, and financial implications of different glycemic control strategies for T1D in pregnant women in Spain.

Materials and Methods

Study population and model

This study is based on a previously developed model in the United Kingdom[22] using results from the AiDAPT trial.[16] Briefly, this RCT recruited 124 pregnant women in antenatal diabetes centers from England, Scotland, and Northern Ireland. Participants were randomized into two groups for the management of T1D: SoC (CGM with MDI or insulin pump) and the AID system CamAPS FX. Spanish population data was retrieved from the Hospital Discharge Records in the National Health System,[23] in which 5561 pregnant women living with T1D between 2009 and 2015 were recorded. Based on this data, an average number of PWwT1D was estimated at 794 per year.

The health economic model was designed to evaluate the clinical and economic consequences associated with variations in maternal glycemic control throughout pregnancy. Specifically, it estimates outcomes linked to changes in HbA1c levels from early pregnancy (≤13 + 6 weeks' gestation) to the third trimester (≥28 weeks). A decision-tree model was implemented, incorporating parallel pathways for obstetric and neonatal events. These branches were stratified according to maternal HbA1c levels measured in the third trimester and categorized into clinically relevant groups: HbA1c <6% (<42 mmol/mol), HbA1c 6%–7% (42–53 mmol/mol), and HbA1c ≥7% (≥53 mmol/mol) (Fig. 1).

To reflect the glycemic effect of CamAPS FX, the HbA1c shift observed in the AiDAPT trial was applied to the baseline (first trimester) HbA1c distribution of the trial population. Risk probabilities for obstetric and neonatal outcomes were then assigned based on the third-trimester HbA1c strata, aligning with the reported differences in glycemic outcomes: a mean HbA1c reduction of 1.8% with CamAPS FX versus 1.5% with standard care.

Outcomes

The model incorporated both maternal and neonatal outcomes that are sensitive to glycemic control in late pregnancy. Obstetric outcomes included the occurrence of preeclampsia and mode of delivery (vaginal birth or cesarean section), as reported in the AiDAPT clinical study.[16] On the neonatal side, the model estimated the length of hospital stay (LOS) across three levels of care: routine postnatal ward, high-dependency care (levels 1–2), and neonatal intensive care (level 3). LOS was treated as a proxy for neonatal complications, such as preterm birth, respiratory distress, neonatal hypoglycemia, macrosomia, or other conditions requiring escalated care.

Costs and time horizon

The economic evaluation was performed from the Spanish health care system's perspective, including direct health care

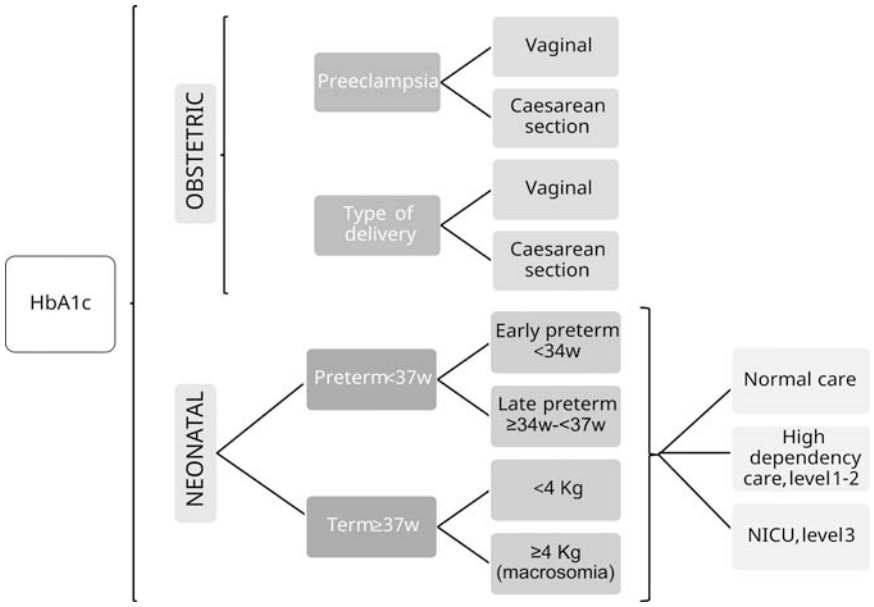

FIG. 1. Model's decision tree, including obstetric and neonatal outcomes. HbA1c, glycated hemoglobin; NICU, neonatal intensive care unit; w, weeks.

costs. Costs were retrieved from three main sources: reimbursement tariffs listed in a Spanish health care cost database,[24] a previous economic evaluation conducted in women of reproductive age,[25] and cost analogies for the LOS of neonates in high-dependency levels 1–2, from the original UK study[22] (Supplementary Table S1). Costs associated with readmission or diabetes management devices were excluded from the economic evaluation due to data constraints. Therefore, this approach was a conservative estimation of the total direct costs associated with immediate health care expenditures and a targeted evaluation of the two treatment strategies. All costs for this model were inflated (and converted) to 2024 euros (€).

Sensitivity analysis

To assess both model uncertainty and variability, a probabilistic sensitivity analysis (PSA) was conducted using Monte Carlo simulations. A beta distribution was applied to the HbA1c effect parameter associated with the CamAPS FX AID system and the SoC distribution, and 1,000 iterations were performed to explore the range of possible outcomes. This approach enabled the evaluation of how variability in the HbA1c effect influences the distribution of PWwT1D across the HbA1c categories within the decision tree. Consequently, the PSA facilitated the estimation of the potential variation in both clinical and economic outcomes resulting from uncertainties in the CamAPS FX AID treatment effect and the SoC treatment effect.

This article has been written according to the ISPOR CHEERS checklist.[26]

Results

Base case analysis

The total health care costs in Spain for the 794 PWwT1D were €10,330,533 with the SoC and €9,534,222 with AID. The estimated cost savings for the Spanish health care system, assuming all PWwT1D used the CamAPS FX AID system, were €796,311. This cost reduction was achieved by reducing obstetric costs from €3,962,931 in the SoC to €3,865,210 in the AID group, neonatal care from €6,167,574 to €5,522,325 in the CamAPS FX group, and doctor visits from €200,027 to €146,687 in the CamAPS FX group (Table 1).

Table 2 shows the health model results for both the original cohort of 794 participants and the extrapolated estimates for 1000 PWwT1D in clinical and economic terms. On a per-1000-women basis, total costs decreased from €13,003,728 with SoC to €12,001,358 with CamAPS FX, resulting in estimated savings of approximately €1,002,369. Neonatal outcomes accounted for 81% of the total cost savings, due to shorter LOS in the high-dependency care unit and the NICU. Specifically, the model projected a 5.0% increase in LOS within standard neonatal care, a 15.8% decrease in high-dependency care levels 1–2, and a 12.4% reduction in NICU level 3 care. These reductions translated into estimated savings of €440,971 and €441,462 per 1000 singleton births, respectively. Regarding obstetric outcomes, CamAPS FX AID was associated with a projected 12.8% reduction in preeclampsia cases compared to SoC, yielding additional savings of €180,844 per 1000 women. According to the third-trimester maternal HbA1c level, the total costs per mother and infant were estimated as €10,742 for HbA1c < 6%, €12,332 for HbA1c ≥ 6%–<7%, and €23,423 for HbA1c ≥ 7%. Total health care costs were dependent on third-trimester HbA1c distribution among groups.

Sensitivity analysis

In a sensitivity analysis, alternative HbA1c distributions for 794 PWwT1D were examined, and total costs were calculated considering the use of AID or SoC. This resulted in a subsequent total cost estimation of €9,520,114 when using AID versus €10,327,624 with SoC (Table 1). Based on this analysis, the potential cost savings for the Spanish health care system in this scenario, when comparing CamAPS FX AID to SoC, were estimated at €807,510 by reducing the percentage of PWwT1D in the groups of HbA1c ≥ 7%. The findings from this sensitivity analysis were consistent with the base case analysis.

Table 1. Costs for the Spanish Health Care System (PWwT1D *N* = 794) by HbA1c Level for Standard of Care Treatment and CamAPS FX AID Treatment

Outcome (unit)	*SoC Costs (€)*[a]	*CamAPS FX AID costs (€)*[a]	*Cost savings*
Obstetric outcomes			
HbA1c < 6%	€1,965,732	€2,352,434	
HbA1c ≥ 6%–<7%	€1,101,219	€1,066,806	
HbA1c ≥ 7%	€ 895,980	€445,970	
Neonatal outcomes			
HbA1c < 6%	€2,521,963	€3,018,087	
HbA1c ≥ 6%–<7%	€1,601,377	€1,551,334	
HbA1c ≥ 7%	€2,044,234	€952,904	
Additional doctor visits	€200,027	€146,687	
Total	€10,330,533	€9,534,222	–€796,311
Total PSA	€10,327,624	€9,520,114	–€807,510

[a]Costs presented in this table reflect the aggregate costs based on the population distribution from the AiDAPT trial. Lower total costs in higher HbA1c subgroups are attributable to the smaller proportion of women in these categories, rather than a lower cost per individual pregnancy.

AID, automated insulin delivery; HbA1c, glycated hemoglobin; PSA, probabilistic sensitivity analysis; PWwT1D, pregnant women with type 1 diabetes mellitus; SoC, standard of care.

Table 2. Outcomes and Costs of the Use of CamAPS FX AID Versus Standard of Care in Pregnant Women with T1D in Spain ($N = 786$) and Extrapolations to 1000 Women

	Outcomes			*Costs (€)*		
	SoC	*CamAPS FX*		*SoC*	*CamAPS FX*	
	1.5	*1.8*	*Difference*	*1.5*	*1.8*	*Difference*
Obstetric outcomes, *n* (794 women)						
Preeclampsia events	96	84	−12.8%			
Vaginal delivery events	130	137	5.8%			
Cesarean section events	568	573	0.9%			
Neonatal outcomes, days (794 women)						
Average neonatal care	1,075	1,129	5%			
Average high dependency (levels 1–2)	1,699	1,432	−15.8%			
Average NICU level 3	1,464	1,282	−12.4%			
Obstetric outcomes, *n* (1000 women)						
Preeclampsia events	121	106	−12.8%	1,410,657	1,229,813	−180,844
Vaginal delivery events	164	173	5.8%	556,750	588,865	32,115
Cesarean section events	715	721	0.9%	3,020,998	3,046,719	25,721
Neonatal outcomes, days (1000 births)						
Average neonatal care	1,353	1,421	5%	1,404,250	1,474,464	70,215
Average high dependency (levels 1–2)	2,139	1,802	−15.8%	2,798,909	2,357,938	–440,971
Average NICU level 3	1,842	1,614	−12.4%	3,560,376	3,118,915	–441,462
Additional doctor visits (1000 women)	1,500	1,100	400	251,788	184,644	–67,143
TOTAL PER 1000 WOMEN						**–1,002,369**

Bold text denotes the total estimated savings.
AID, automated insulin delivery; NICU, neonatal intensive care unit; SoC, standard of care; T1D, type 1 diabetes.

Discussion

This economic evaluation provides compelling evidence supporting the use of CamAPS FX AID during pregnancy. From the Spanish health care system perspective, achieving lower third-trimester HbA1c translates into estimated savings of around €1,002 per treated woman. These savings are primarily driven by reductions in preeclampsia rates and improved neonatal outcomes, resulting in decreased need for intensive neonatal care.

Beyond the economic benefits highlighted in this study, providing pregnant women with tools specifically designed to manage the complex and dynamic physiological changes of pregnancy is crucial. This period, while medically challenging, is also a uniquely special time in life and should be experienced with reduced burden of diabetes management. By enabling improved glycemic management, CamAPS FX may support maternal well-being and play a critical role in giving neonates a healthy start in life, potentially minimizing the risk of complications associated with maternal diabetes.[27]

The findings of this study are in line with data from the UK health care system, where estimated savings of £920,000 per 1000 PWwT1D were reported under similar modeling conditions.[22] In comparison, Azahaf et al.[18] reported lower projected savings of €232,570 per 1000 pregnancies when assessing a different AID system. The variation in savings may be partly explained by methodological differences, such as the inclusion of the device acquisition costs, or differences in baseline population characteristics. Notably, the CRISTAL trial had lower baseline HbA1c levels in both study arms, which limits the potential for improvement.[20] Consequently, the AID system assessed in their study showed modest improvements in glycemic control, without significant differences in overall TIRp,[20] which likely constrained the potential for cost savings related to complication avoidance. However, current evidence suggests that CamAPS FX is the most effective AID system for rapidly optimizing maternal glycemia during early pregnancy,[28] a factor likely driving the higher economic benefits observed in this study.

Our decision-tree model attributed 81% of total cost savings to improved neonatal outcomes, primarily due to a reduction in LOS in high-dependency units and NICU. Specifically, CamAPS FX use yielded savings of €1,002,369 per 1000 women through decreased LOS in these specialized care settings. While there was an increase in standard neonatal care costs—likely reflecting earlier transfers from intensive care to lower-dependency wards before final discharge—the overall economic impact remains favorable for the health care system. The reduced burden on high-dependency neonatal care and NICU not only diminishes direct medical costs but also alleviates strain on critical health care infrastructure. This redistribution of neonatal LOS is supported by a recent network meta-analysis of glucose-lowering interventions, which reported reduced NICU admissions and LOS.[29]

In terms of obstetric outcomes, there was a projected reduction in preeclampsia cases with CamAPS FX use compared to SoC, generating additional savings. These immediate clinical benefits illustrate how improved maternal glycemic control can also translate into broader health care system advantages.

Beyond maternal complications, glycemic control during pregnancy is also crucial for neonatal outcomes. Previous research has established strong associations between improved maternal glycemic control, lower neonatal glucose exposure, and decreased NICU admissions and LOS.[30] Furthermore, the

Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study[31] demonstrated that even mild maternal hyperglycemia below diabetic thresholds correlates with heightened neonatal morbidity requiring intensive care, underscoring the importance of maintaining tight glycemic control during pregnancy.

Our findings suggest that CamAPS FX may have benefits extending to the preconception and postpartum periods. The implementation of this technology in the preconception period could enhance maternal metabolic status before conception, further improving neonatal and maternal outcomes.[32,33] Additionally, postpartum evaluations of continued CamAPS FX use in women with T1D after delivery have reported positive impact on TIRp, reduction of hyperglycemia, and safety, supporting its role in long-term diabetes management.[34]

This study presents limitations. The evaluation excludes additional cost drivers related to clinical outcomes, such as neonatal readmissions, birth injuries, or postpartum maternal care, meaning that the cost savings estimates are likely conservative. Direct costs of the management technologies themselves (devices and apps) are not considered, taking into account the scope of the study, whose focus lies on the evaluation of outcomes rather than on a full economic appraisal. Our aim was to explore how the adoption of the technology may influence clinical outcomes, and how these, in turn, may translate into cost differences. Additionally, LOS was used as a proxy measure for birth-related complications, assuming that an extended LOS is a direct result of these complications. Overall, the conservative approach applied in this study likely underestimates the true cost savings, providing a cautious estimate of the potential economic impact of AID systems on the Spanish health care system.

This analysis confirms that CamAPS FX can contribute to both improved clinical outcomes and economic efficiency in managing PWwT1D. Especially in publicly funded health care systems with limited neonatal intensive care capacity, such as Spain, these benefits are particularly salient, providing a strong rationale for widespread adoption of this pregnancy-approved AID system. These findings may help accelerate the adoption of appropriate AID systems during pregnancy, ensuring more women and infants benefit from optimized diabetes care during this crucial period.

Conclusions

This economic evaluation shows that use of the CamAPS FX AID system has the potential to provide significant cost savings for the Spanish health care system. These findings support the option for use of CamAPS FX AID in routine clinical practice for PWwT1D with a discussion of the pregnancy-specific targets, which could represent a crucial step forward in equitable cost-effective diabetes care. Given the unique demands of pregnancy, it is vital to provide tools that reduce maternal complications and diabetes-related stress and give newborns the best possible start in life.

Authors' Contributions

Conceptualization: M.-E.S. and A.K.-M. Study design and methodology: M.-E.S. and A.K.-M. Data collection and resources: M.-E.S., T.T.M.L., and H.R.M. Formal analysis: M.-E.S. and T.T.M.L. Results interpretation: M.-E.S., A.K.-M., T.T.M.L., H.R.M., E.M.S., P.I.B.-V., and C.Q. Original draft writing: M.-E.S. and A.K.-M. Critical input and revision of the article: M.-E.S., A.K.-M., T.T.M.L., H.R.M., F.C., E.M.S., P.I.B.-V., and C.Q. Project supervision: M.-E.S., A.K.-M., and H.R.M.

Author Disclosure Statement

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Supplementary Material

Supplementary Data

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